FRAUD, WASTE, AND ABUSE IN THE MEDICARE PACEMAKER INDUSTRY

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

SECOND SESSION

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CONTENTS

	Page
Opening statement by Senator John Heinz, chairman	1
Statement by Senator Lawton Chiles	3
Statement by Senator Larry Pressler	4
Statement by Senator William S. Cohen	5
Statement by Senator Charles E. Grassley	6
Statement by Senator David Pryor	7
Statement by Senator David Durenberger	8
Statement by Senator Pete V. Domenici	9

CHRONOLOGICAL LIST OF WITNESSES

Panel No. 1. Medicare beneficiaries:	
Garman, Madeline, Sarasota, Fla	11
Alderman, Edna L., Tucson, Ariz., accompanied by Gregory G. Wasley, Esq	16
Panel No. 2. Pacemaker representatives:	
Hofferman, Howard F., Denver, Colo	30
Stanley, J. Richard, Houston, Tex	36
Panel No. 3. Physicians:	
Furman, Dr. Seymour, Montefiore Hospital and Medical Center, New York, N.Y	50
Blum, Dr. Mark F., Colorado Springs, Colo	57
Kowey, Dr. Peter, director, coronary care unit, Medical College of Pennsylvania, Philadelphia, Pa	58
Phibbs, Dr. Brendan, chief of medicine and director of cardiology, Kino Hospital, Tucson, Ariz	60
Panel No. 4. Manufacturers:	
McFarlin, Whitney A., corporate vice president, pacing systems group, Medtronic, Inc., Minneapolis, Minn	78
Chambers, Russell, president and chief executive officer, Intermedics, Inc., Freeport, Tex	87

APPENDIXES

Appendix 1. Bills of pacemaker recipients:	
Item 1. Initial bill of Madeline Garman	105
Item 2. Replacement bill of Madeline Garman	112
Item 3. Initial bill of Willie A. Meadows	119
Item 4. Replacement bill of Willie A. Meadows	129
Appendix 2. Material related to hearing:	
Item 1. Letter from Dr. Brendan Phibbs, chief of medicine and director of cardiology, Kino Community Hospital, Tucson, Ariz., to Senator John Glenn, dated September 14, 1982	132
Item 2. Letter from Thomas P. Finley, executive director, Greater Southern Arizona Professional Standards Review Organization, Tucson, Ariz., to Senator John Heinz, chairman, U.S. Senate Special Committee on Aging, dated October 15, 1982	133
Item 3. Letter from Merritt W. Jacoby, executive director, medicare A administration, Blue Cross and Blue Shield Association, Chicago, Ill., to Senator John Heinz, chairman, U.S. Senate Special Committee on Aging, dated November 5, 1982	134

Appendix 2. Material related to hearing—Continued Page
Item 4. Letter from Glenn A. Shimmel, assistant vice president, medicare programs, Blue Cross and Blue Shield of South Carolina, Columbia, S.C., to Senator John Heinz, chairman, U.S. Senate Special Committee on Aging, dated October 21, 1982 135
Item 5. Letter from Thomas A. Levin, president, Blue Cross and Blue Shield of New Mexico, Albuquerque, N. Mex., to Senator John Heinz, chairman, U.S. Senate Special Committee on Aging, dated October 28, 1982 135
Item 6. Department of Health and Human Services draft audit report, September 3, 1982 137
Appendix 3. Material submitted by witnesses:
Item 1. Letter and enclosure from Whitney A. McFarlin, corporate vice president, pacing systems group, Medtronic, Inc., Minneapolis, Minn., to Senator John Heinz, chairman, U.S. Senate Special Committee on Aging, dated October 1, 1982 146
Item 2. Intermedics, Inc., Freeport, Tex., response to U.S. Senate Special Committee on Aging study (information paper) on fraud, waste, and abuse in the medicare pacemaker industry, dated October 21, 1982 157

FRAUD, WASTE, AND ABUSE IN THE MEDICARE PACEMAKER INDUSTRY

FRIDAY, SEPTEMBER 10, 1982

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, D.C.

The committee met, pursuant to notice, at 9 a.m., in room 318, Russell Senate Office Building, Hon. John Heinz (chairman) presiding.

Present: Senators Heinz, Domenici, Cohen, Pressler, Grassley, Durenberger, Chiles, Glenn, Melcher, Pryor, and Burdick.

Also present: John C. Rother, staff director and chief counsel; Becky Beauregard, deputy staff director; Bill Halamandaris, director of oversight; David Holton, chief investigator; Kate Clarke, communications director; Kathleen M. Deignan, minority professional staff member; Robin L. Kropf, chief clerk; Angela Thimis, staff assistant; and Eugene R. Cummings, printing assistant.

OPENING STATEMENT BY SENATOR JOHN HEINZ, CHAIRMAN

Senator HEINZ. The committee will come to order.

Today's hearing marks the culmination of a yearlong investigation conducted by the committee staff of problems related to the purchase and use of pacemakers under the medicare program.

Medicare costs associated with pacemaker procedures include the cost of the pacemaker, hospitalization, and related medical procedures associated with the prescription of a pacemaker, its implantation, followup care, and monitoring. Apparently, medicare reimburses these costs without questioning either appropriateness or necessity. The committee staff report I am releasing today details costs at every level associated with the purchase and use of pacemakers are excessive.

Manufacturers, for example, commonly bill and are paid for list prices 400 to 500 percent greater than the cost of the pacemaker. Hospitals mark up the device as much as 50 to 150 percent without any correlating expense. Sometimes these pacemakers are on consignment.

Physicians charge $1,000 to $2,500 for implanting pacemakers and are reimbursed based on fee schedules established at a time when the surgical procedure was several times more difficult and time consuming than at present.

Pacemaker followup services are particularly lucrative, since salesmen frequently provide the necessary equipment "free of charge," set up the monitoring system, train personnel and provide

medicare billing information. One salesman told the committee, "You can make a quarter of a million dollars doing this in a couple of years, and all it costs you is stamps."

Pacemaker warranties for defective devices are practically inoperative under medicare, forcing medicare to carry the burden of at least 90 percent of all replacement costs. The necessity and appropriateness of many pacemaker procedures is also increasingly questioned. Estimates of overutilization range from as little as 10 percent, as we will hear today, to as much as 80 percent of all pacemakers implanted. The most frequent projections are that 30 to 50 percent of the pacemakers prescribed are not necessary.

Kickbacks, rebates, and other inducements to do business are freely offered. Among the inducements identified by the committee are the direct cash payments of $150 to $200 for each pacemaker implanted; stock or stock options offered as a reward for dubious "consulting" arrangements; the "gift" of necessary pacemaker accessories ranging in cost from several hundred to several thousand dollars as an inducement to do business; fishing excursions to Alaska, ski trips to Colorado, Las Vegas gambling junkets, and vacations in the Caribbean.

Beyond these questions lie other issues of equal concern. These include the ability of the FDA to track pacemaker performance and protect medicare beneficiaries, questions relating to the professional preparation of pacemaker physicians, and their undue reliance on pacemaker salesmen. The committee estimates the pacemaker salesman is in the operating room, attending and assisting in these operations, about three-quarters of the time.

The magnitude of the problem before us requires immediate action. When all of the cost elements are reviewed, as much as half of the $2 billion total that medicare spends for pacemakers and related professional services each year can be questioned as unnecessary.

I am calling today for the formation of a task force to include representatives of the Department of Justice, the Internal Revenue Service, the Securities and Exchange Commission, and the FBI, to pursue the allegations of criminality associated with the use of pacemakers under the medicare program. Specific evidence of criminal violations identified by the committee has already been transmitted to the FBI.

In addition, I will request the General Accounting Office to initiate an intensive review of the cost associated with the use of pacemakers under the medicare program. The GAO will be reviewing the relation between the manufacturer's cost and the cost ultimately borne by the medicare program. Particular attention will be paid to the question of the manufacturer's obligations under warranty provisions.

Finally, I have transmitted a copy of the committee's report to Secretary Schweiker with the request that the departmental task force announced on Sunday to look at pacemaker problems should be expanded to include representatives of the FDA, and that the task force mandate be enlarged to address all the medicare utilization and payment questions raised by this report.

Before we hear from our witnesses, I want to recognize the ranking minority member of our committee, Senator Lawton Chiles,

who has been very much involved in this investigation, and indeed, one of whose constituents, whom we will hear from later, had a very pivotal role in bringing this directly to his and the committee's attention.

Senator Chiles.

STATEMENT BY SENATOR LAWTON CHILES

Senator CHILES. Thank you, Mr. Chairman. I want to say that I am delighted to see the work that you and the committee have done in bringing forth this hearing.

A year ago, Madeline Garman, a medicare beneficiary, wrote a letter to me. She was angry about what she thought was a ripoff of medicare when a pacemaker that she had was recalled and had to be replaced.

Her action helped focus this committee's attention on what we now estimate could be as much as $1 billion a year in inappropriate medicare payments for pacemakers, pacemaker surgery, and followup.

Mrs. Garman is here today, and she will tell us her story. Her question to me was a very basic one: If a pacemaker is under warranty of 10 years, and 2 years later it is recalled and replaced, why does medicare pay the full cost of a new pacemaker? Why doesn't the manufacturer pay?

In her own words, she said, "How many hundreds of these were called in over the country, and how many thousands of dollars spent by medicare? It is one of the ways medicare is being milked, and I am incensed over it. When a car is called in, there is no expense to the customer. Why this?"

Her analogy is certainly a very good one, and in this case, the customer is medicare.

During our investigation, we found out that almost one-third of all pacemaker operations in any one year are for replacement of failed pacemakers or parts. We found that many warranties, in effect, rely on medicare and other insurers to pay the full cost of the new pacemaker, as well as all surgical and medical expenses.

The only part of many pacemaker warranties actually honored is a small amount to cover "uninsured medical expenses"—regardless of fault, performance, or recall. In effect, medicare ends up holding the bag for pacemaker product liability, and Mrs. Garman was right: It is a ripoff.

But it turns out that was only the tip of the iceberg. We found much more. Charges for pacemakers are grossly inflated, anywhere from 400 to 500 percent, all paid for by medicare. Enough salesmen and doctors find pacemaker profits so alluring that medical experts estimate that as much as 30 to 50 percent of all pacemaker implants may not be necessary. Kickbacks of cash, company stock, expensive gifts, and vacations from companies and salesmen to doctors to get them to use their product have been acknowledged by those in the business. Some pacemaker salesmen, in effect, set up doctors in large pacemaker practices. They offer training, they donate equipment, they advise on how to get the most out of medicare for it all.

The relationship is so close that pacemaker salesmen are actually present in the operating room, assisting the surgeon, in up to 75 percent of all pacemaker operations done in the country.

There is a fine line, perhaps, between what might be considered acceptable marketing practices and improper inducements in any business. But when medicare is paying the bill, we have to be extra careful. We cannot afford to continue this way.

I think, Mr. Chairman, much of what we have uncovered is clearly against the law.

Senator HEINZ. Senator Chiles, thank you for that excellent statement.

Under the "early bird" rule, Senator Pressler is recognized.

STATEMENT BY SENATOR LARRY PRESSLER

Senator PRESSLER. Thank you, Mr. Chairman. I want to commend you, and the staff, and Senator Chiles, for the work that has been done. Upon reviewing the details of the investigation's findings, I was somewhat amazed to see the many forms that fraud can take in this area. It seems that pacemakers are not only being implanted unnecessarily, but some doctors and hospitals are overcharging for their services, and new pacemakers are often implanted without reference to warranties. In addition, doctors appear to be receiving kickbacks for using a particular company's pacemakers, and the company salesmen may actually assist at surgery. All this is apparently done without any of the participants considering the cost to the medicare system, which pays for 80 to 90 percent of the pacemaker implants in this country.

The total bill for this procedure under medicare this year will reach approximately $2 billion, and investigators estimate that as much as half of these payments may be questionable. I find it hard to believe that physicians and hospitals participate in this type of corruption, but I understand that these practices are widespread nationally. Medicare recipients in South Dakota, as well as elsewhere, have a right to expect that these funds are spent on necessary and appropriate health care.

Let me add that I am sure we will hear the side of the manufacturers, because there is no doubt a great deal of liability insurance, and a possibility of being sued by those who supply these instruments. Part of the high cost may be due to some of the huge jury awards that may be given if there is found to be liability. We also should look into the cost of the insurance for liability that these companies have.

Nevertheless, in spite of these things, what the investigators have turned up certainly demands explanation, and the extremely high markup demands an explanation. And I am sure that we will be hearing from both sides.

I look forward to hearing this testimony from our witnesses this morning, and I hope as a result of this hearing, we are able to see that this situation is rectified.

Senator HEINZ. Senator Pressler, thank you.

Senator Cohen.

STATEMENT BY SENATOR WILLIAM S. COHEN

Senator COHEN. Thank you, Mr. Chairman, and I add my commendation to you for holding this hearing and for producing the report.

It seems to me that this report reveals a pattern of abuse which is almost endemic in our system. Last year, we had hearings involved with the fraud and waste involved in home health care provisions for our elderly. We found that millions of dollars are being spent for nonprofit shells, for unscrupulous individuals who are using the money to invest, as I recall, in oil exploration off the coast of Costa Rica. The problem was that no one cared. We had intermediaries, Blue Shield, Blue Cross; we had HCFA, the agency that was supposed to be responsible for oversight on this. No one was responsible, and no one was conducting oversight—there was no audit. It was an attitude of just pass the bills, and Uncle Sam will pay them.

It seems to me we have a similar situation right here with the pacemaker industry. I talked with a prominent senior citizen in my home State yesterday, and that individual told me that he had had a pacemaker implanted, and had it not been for the insurance, he would have been financially ruined. It cost something like $4,000. Well, $4,000 is usually beyond the reach of most people in my State and, I suspect, in many other States. So the bill would have to be picked up by insurance, and most prominently, medicare, and medicare dollars which are growing in very short supply are being wasted by unscrupulous individuals.

It seems to me that one of the most fundamental things that I noticed in this report is there is very little concern on the part of individuals about the care of the patient, whether that patient needs it—and indeed, as your report points out, some physicians have even resorted to implanting two. It is like buying a new car. We are going to put an extra battery in your trunk in case the first battery runs out. So we have some physicians implanting two pacemakers. It seems to me that throughout all of this, the kickbacks, the fraud, the schemes, the means of ripping off medicare, very little attention is being paid to the patient and concern about his or her welfare.

I think it is summed up, Mr. Chairman, by the report itself, where one of the pacemaker sales representatives said: "Much of the industry is totally unconcerned with price, couldn't care less. Medicare reimburses, and they just do not care. God bless them, I love it."

That is the general attitude, I think, on the part of much of those who have tried to serve our elderly, not only in this particular facet of it, but in the home health care industry as well. It seems to me that the fundamental failure, as you point out in your report on page 3, is because of a fragmentation of Federal responsibility, nobody seems to be in charge, nobody is charged with responsibility, and therefore, there is no responsibility. Indeed, the one agency that is perhaps the most responsible for oversight with primary responsibility is the Department of Health and Human Services, and the report points out they are perhaps the Depart-

ment devoting the least amount of attention to this particular abuse.

So I hope, Mr. Chairman, out of these hearings we will have some positive recommendations that we will follow up and try and arrest the scandalous waste of the taxpayers' money in addition to the abuse of the patients themselves.

Senator HEINZ. Senator Cohen, thank you. I would just like to echo one thing you said before I call on Senator Grassley, as well as to bring the members of the committee up to date.

Yesterday, we had a screening of some of the undercover work done by the committee investigators. The committee investigators had an opportunity to talk to more than a dozen salesmen in this industry in two cities in the United States. In the course of the taping of one of those conversations, where our committee staff was posing as potential direct purchasers of these pacemakers, we saw instance after instance where the only subject that was really talked about was how much money the medical institution or the doctor could make getting into the pacemaker business.

Now, no doubt there are many honest people in the medical profession who are involved with pacemakers, and many very scrupulous and honest hospitals and medical institutions. But it struck me how remarkable it was, as you saw hour after hour of these films, how the only subject that seemed to predominate was how much money you could make and how little attention, if any, was ever paid to what was the benefit that was going to be to the patient—let alone, of course, as to whether anything was going to be economical.

I know Senator Domenici, who has just arrived, was there, Senator Chiles was there, Senator Pryor was there, and a number of others were, but I wanted to say that your observations are very well taken, as the evidence presented by the investigators, I think, demonstrates.

Senator Grassley.

STATEMENT BY SENATOR CHARLES E. GRASSLEY

Senator GRASSLEY. Thank you, Mr. Chairman.

Obviously, there probably has to be some changes made within Government itself to correct these abuses. On the other hand, let me say that I suspect that right here in this room, in the private sector, there are interests who, if they want to clean this mess up, and I would suggest that they should want to, and that they will, that the problem can be taken care of as well there.

Witnesses here this morning will bring us testimony that will doubtless expand on the information you have presented concerning the excesses of the pacemaker industry and the medical profession itself, Mr. Chairman. Yet the purpose of this hearing will be ill-served if the media present send out only that one message. For much more is involved than the fact that yet another element of our society is exploiting the Federal Government in its own interests.

I hope that we on the committee are going to hear witnesses not only confirm the activities outlined in this report, but offer the full-fledged support of the industries, organizations, and profession-

al associations they represent in cleaning up this shoddy and self-serving state of affairs. Nothing could be less rewarding, less useful than to hear only a parade of excuses, buckpassing, and the tired explanation that, "There are only a few isolated cases of abuse."

Many of the witnesses belong to associations who lobby actively in the Senate on a wide range of legislative issues. This Senator, for one, sees merit in such energetic, informative lobbying. On the other hand, I say to those witnesses most deeply involved in the matters being aired this morning, to turn their energy inward, lobby among themselves, and heal this eminently treatable sickness. This committee has provided, through the leadership of our chairman, the examining room, and now it is up to the physician to "heal thyself."

Senator HEINZ. Senator Grassley, that is a most eloquent statement. We thank you.

Senator Pryor.

STATEMENT BY SENATOR DAVID PRYOR

Senator PRYOR. Mr. Chairman, I have a statement I would like to submit for the record, a little longer statement on this matter.

Senator HEINZ. Without objection.[1]

Senator PRYOR. I would like to compliment you, Mr. Chairman, and the staff of the committee for the very splendid work that they have done in the report that they have made available to this committee and to the public.

Mr. Chairman, I did not see one of these until yesterday afternoon, but this is a pacemaker, and this is what we are talking about. [Senator Pryor is holding a pacemaker in his hand.] This item, according to the report by a very competent staff, probably costs somewhere in the neighborhood of $600 to $900 to manufacture. By the time the patient, the public, the medicare system, and certainly, everyone involved, pays for it, this could be as high as $18,000. We have seen case after case of this taking place.

I think what I drew from the feeling yesterday of the meeting that we had, and seeing the films we saw, it came to my mind that perhaps sicker than the patient who is needing this implant, who is needing this pacemaker, is probably the system itself that allows, promotes, and in fact encourages this abuse and fraud to take place.

I think, too, Mr. Chairman, and my colleagues on the committee, that we have got to expeditiously and efficiently go forward with a full investigation of this matter. However, I think on the same hand, we should not be guilty of blanketing in with an accusation across-the-board of every physician and every doctor, because we know that this is not the case, but we know that there is extensive fraud and abuse, and we have got to root that out, and we have got to change the system.

I compliment you for the work you have done and for the very, very fine work the staff has done in this matter. I appreciate the opportunity to participate.

Senator HEINZ. Thank you, Senator Pryor.

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[1] See next page.

[The prepared statement of Senator Pryor follows:]

PREPARED STATEMENT OF SENATOR DAVID PRYOR

Mr. Chairman, I am pleased to be here today as the Special Committee on Aging focuses its attention on fraud and abuse in the medicare pacemaker industry. The investigation into this issue is long overdue, and I can think of no more appropriate body to examine these abuses than this committee, which has such an excellent record in uncovering frauds in programs which have been established for the benefit of older Americans.

Mr. Chairman, I was shocked when I learned of some of the practices—both "legal" and illegal—which are being carried out in this industry. First, the markup on the device itself. The committee investigation has revealed that, although the average pacemaker costs only about $600 to $900 to manufacture, hospitals are often charged as much as $5,000 per unit. But this is only the beginning. Additional markups, physician fees, and related followup charges can add up to where medicare can be charged as much as $18,000 per implantation. And, should the unit fail, in almost no case is the warranty upheld. Instead, medicare or the insurance firm is just charged for another unit.

Investigators have also found that in many cases physicians are offered kickbacks in the form of "consulting fees," free vacations, stock options, free equipment, and the like, as inducements to do business with a specific company. And, if that's not enough, the firms often offer to "train" the physician unskilled in pacemaker implantation in order to get his business. In nearly 75 percent of all cases, the salesman himself is present in the operating room to "assist" the physician.

One of my chief concerns about these ongoing abuses is that, at a time when the medicare budget is expanding at such a dramatic rate, and the administration is working so diligently to reduce much needed benefits, as much as 2 percent of the medicare budget may be being so unnecessarily wasted. This situation must be changed.

One of the most disappointing aspects of this issue is that, despite its clear and direct responsibility, the Department of Health and Human Services seems to be expending only minimal efforts toward elimination of these abuses. What other reason would explain the fact that these practices have been an ongoing occurrence? And although many other agencies (such as the Veterans Administration, the Securities and Exchange Commission, the General Accounting Office, the Federal Trade Commission, and the Federal Bureau of Investigation) have conducted their own probes, no efforts have been made to "join forces" to effect a change.

Hopefully, the combined revelations of this committee's able investigative staff and the testimony we hear today will go a long way toward the speedy correction of this deplorable situation. I look forward to hearing today's testimony.

Senator HEINZ. Senator Durenberger.

STATEMENT BY SENATOR DAVID DURENBERGER

Senator DURENBERGER. Thank you, Mr. Chairman.

I apologize for being late, and I want to start by congratulating you on not only the hearing, but the year-plus of work that went into the hearing.

The fraud, waste, and abuse that you have uncovered, Mr. Chairman, helps us focus, I think, on what I think is the heart of the problem.

We can dump on the manufacturers, we can dump on their salesmen, we can sic the FBI on them, and we can have task forces coming out of our ears at HHS, but the heart of the problem is right here, on this side of this green table. For too long, we have been sitting here, saying we can somehow regulate this health care system. You know, we want to provide health care for all Americans, regardless of the cost, and when the costs get up too high, then we start putting the clinches around the manufacturers, around the providers, around the doctors, around the insurance companies, around whomever is in reach.

Mr. Chairman, you well know that it takes this kind of attention for us to look at the heart of the problem, which is the way we reimburse for health care and for sick care. The CHAMPS proposal of yours that was on the tax bill this year—that nobody knows anything about—is the forerunner for preventing the kinds of things that we will be hearing about this morning from happening. The prospective payment system that HHS is working on will also help prevent these things from happening.

So it is not just a matter of setting up some guidelines, which we should do. It is not just a matter of our putting pressure on the American Medical Association and the physicians of this country to start looking at the way they utilize high technology and the way—in effect—they abuse the system and increase costs in the system.

It really means that all of us on this side of this green table have to start paying some attention to the way the people of this country provide for their health care, and when they are unfortunate enough to be ill, how they provide for their sick care.

I commend you, Mr. Chairman, not only for calling attention to a specific portion of the problem, but also for your continuing care and interest in changing the way this whole health care system works.

Senator HEINZ. Senator Durenberger, I would be remiss if, in recognizing your kind remarks, if I did not point out to the observers here that whatever the rest of us have done in regard to changing the incentives in the health care system, they are really very, very modest in comparison to what you yourself have been trying to do. I think you have demonstrated a tremendous amount of foresight and an enormous amount of political courage in advocating far-reaching changes and incentives in the health care system.

I do not know of anybody on Capitol Hill who has worked harder in that regard, and who has had more vision in that regard, than you. I just want the record to be very, very clear, notwithstanding your kind remarks about other people.

Pete Domenici, Senator Domenici.

STATEMENT BY SENATOR PETE V. DOMENICI

Senator DOMENICI. Mr. Chairman, I too, apologize for being late, and I want to compliment you and the staff. I think Senator Durenberger has said it correctly. I was reviewing the staff report, and there is a quote in there that epitomizes the problem. One of the salesmen said, Mr. Chairman, and I quote, "The industry is totally unconcerned with price, couldn't care less. Medicare reimburses, and they just don't care. God bless them, I love it." That is a quote from one of the salesmen from the record.

I am fully aware, as are most of you, of what has happened to medicare. It is only the fastest growing domestic program of all domestic programs. Even with all the savings that have been accomplished through the last reconciliation bill, it will grow at 13, 13½ percent. It will go up $8 billion this year all by itself. It will reach $58.2 billion in 1983, even with forced savings of about 3 percent brought about by the work of the Finance Committee and the Congress.

We may need criminal prosecutions, indictments, but I think unless we eventually solve the problem, costs will continue to climb. Cost-based reimbursement is at the core of this problem because medicare, with little scrutiny, will pay the reasonable cost of a device or a service in the hospital, and as a result of this, there is simply no incentive to control costs. Therefore, the kind of excessive markup and profits which have been uncovered by this hearing are just the natural result of the cost reimbursement system.

That salesman was right. We have created a law which could care less about cost and thus, stimulates everyone to get in on the gravy train. The staff report, to cite another example, indicates that a device which costs $600 to $900 to produce is sold for $3,000 to $5,000. There are indications that as much as 50 percent of that sales price may be going to sales activities. These activities, some of which may be illegal, include treating potential buyers to training related ski trips or boat rides. Reimbursement for these vacations is added to the price of the pacemaker, as part of that reverse incentive that we have built into the system. The salespeople know that medicare will pay the inflated price. Whether it is criminally illegal or not, it is time that we understand that this is not the way to provide health care for the American people, and it is no wonder that with this kind of approach to cost-based reimbursement, that medicare will be bankrupt within 3 years.

Thank you, Mr. Chairman.

Senator HEINZ. Senator Domenici, thank you very much.

[The prepared statement of Senator Domenici follows:]

PREPARED STATEMENT OF SENATOR PETE V. DOMENICI

Mr Chairman, I would like to commend you for calling this hearing to publicize and expose the scandal in medicare reimbursement for heart pacemakers. The staff paper we issued this morning, in fact, quotes one salesman of pacemakers as saying, "The industry is totally unconcerned with price—couldn't care less. Medicare reimburses and they just don't care. God bless them, I love it." I believe that the record of this hearing, along with the excellent information paper prepared by the staff, will create the impetus to reform medicare to eliminate this kind of abuse.

As chairman of the Budget Committee I am acutely aware of fiscal implications of this issue, Medicare is the fastest growing domestic program. Increasing at a rate of 13.3 percent, it will grow by over $8 billion in 1983 alone, and will cost the taxpayer $58.2 billion. This increase will occur in spite of the saving achieved as a result of the Tax Equity and Fiscal Responsibility Act recently passed by Congress.

The abuses raised by the information paper and by the briefing I received yesterday may lead to criminal indictments. Equally as important, however, they indicate that the structure of medicare itself has fostered these abuses. The problem is "cost-based reimbursement." That is, medicare, with little scrutiny, will pay the "reasonable cost" of a device or service in a hospital. As a result, there is simply no incentive to control cost, and the kind of excessive markup and profits which have been uncovered are the natural result.

As the salesman I quoted above stated, there is no concern with price; they couldn't care less about it. Medicare will pay the cost, and they love it. As another salesman explained, it is to the hospital's advantage to purchase the most expensive devices possible. "It's a clinical decision, but clinically what are you really getting for more money? One thing you get for more money is establishing a higher reimbursement base."

I am pleased to note that the reforms we recently enacted in medicare directly address this reimbursement problem and, I believe, represent a major step to change the incentives in medicare toward increased cost consciousness.

The staff paper indicates that devices which cost $600 to $900 to produce are sold to hospitals for $3,000 to $5,000. As much as 50 percent of that inflated price is used for marketing. (Hospitals, not to be outdone, add an additional markup of 50 to 150 percent.) This "marketing activity," reimbursable under medicare, includes kick-

backs, "training programs" including Las Vegas shows, and the Dallas Cowboy Cheerleaders, trips to Vail, Colo., for skiing, Las Vegas gambling junkets, and other abuses.

Most important, and most frightening, there is ample evidence that the huge profits cause the use of pacemakers when other less costly and less dangerous remedies would be equally effective. As the report notes, "* * * the use of pacemakers (in the United States) is more than twice that of the next highest user in the free world. * * * Applications * * * have been significantly expanded * * * to include a variety of ambiguous conditions where the prescription of pacemaker therapy is of questionable value."

The report amply demonstrates that we in Congress, through the perverse reimbursement formula until recently included in medicare, have fostered these abuses. There are essentially no controls on the price of pacemakers and, as a result, funds which could serve to treat patients are squandered on an array of frivolous, if not illegal, activities. More disturbing yet, is the evidence that huge financial windfalls are effecting the use of pacemakers—possibly to the detriment of the patients.

Mr. Chairman, again my congratulations for your efforts in this area and I look forward to hearing from our witnesses.

Senator HEINZ. I would like to call our first witnesses to the table: Madeline Garman, Gregory Wasley, and Edna Alderman.

While they are coming, I just want to observe that Senator Domenici has done more than anyone else to try and curtail the growth of Federal spending programs. I know how hard he worked as chairman of the Budget Committee to do that. And I suppose he feels the same way I do, when I see a system that is out of control. The way I feel is that we are being asked to try somehow to solve a problem, grasping the tip of the iceberg to try and move it, when the iceberg is unseen, unfocused upon, and unchanged by all our scrambling about on the surface. It is the waste that really does the Government in. Yes, there is fraud and abuse in this program, but the way the medicare program is structured invites waste, as Senator Durenberger in particular pointed out.

I would like Senator Chiles to, if he would, introduce Mrs. Garman, his constituent, to the committee.

Senator CHILES. Thank you, Mr. Chairman.

I really enjoy the opportunity to introduce Mrs. Garman to the rest of the committee. Before she retired, Mrs. Garman spent many years as a nurse, a social worker, and as a Red Cross executive in Illinois and Indiana. She is here today with her daughter, Mary Jane Jerkins. I certainly think Mrs. Garman is to be congratulated. She, like many other medicare beneficiaries, reads about budget cuts, Pete, and cuts in medicare, and then she sees copies of the bill that medicare has paid, and she knows why medicare is in trouble.

Mrs. Garman is very conscious of health care costs, and when she saw something she thought was out of line, she tried to do something about it.

Mrs. Garman, we are delighted to have you here today, and we want you to tell us what happened to you and why you wrote us the letter.

PANEL NO. 1. MEDICARE BENEFICIARIES

STATEMENTS OF MADELINE GARMAN, SARASOTA, FLA., AND EDNA L. ALDERMAN, TUCSON, ARIZ., ACCOMPANIED BY GREGORY G. WASLEY, ESQ.

Mrs. GARMAN. Members of the Committee on Aging, my name is Mrs. Madeline Garman. I am 89 years old, and I am from Sarasota,

Fla. I have a heart condition, and it is necessary that I wear a pacemaker to regulate my heartbeat.

I recently had an experience which made me angry, and it prompted me to write a letter to Senator Chiles. That was on September 14, 1981. I think the best way for me to tell you my story is to read you the letter I wrote to him [reading]:

"Dear Senator, You may not be the one to handle this problem, if not, you will know who to give it to. We have heard a great deal about the problems of medicare, and my problem relates to it.

"In 1979, I had a pacemaker transplant at the Sarasota Memorial Hospital, done by Dr. R. W. Hoefer, and the pacemaker furnished by the Intermedics, Inc., of Freeport, Tex., and guaranteed for 8 years.

"This spring, I was notified by the doctor that the model I had was giving trouble, and the company called all in, at their expense, and we were given 6 months to have them replaced.

"The doctor examined all he had implanted, how many, I could not find out. He took those not working properly first, and I was one of them, and I was again assured, 'at no cost' to me.

"The company, Intermedics, Inc., sent me a check in the amount of $450 to cover expenses not covered by my insurance, knowing by my age of 88 years that it was medicare who would be billed. My hospital bill was $5,426.50, and the pacemaker alone was $3,900. The doctor's bill was $505, and there were several lab bills. Of course, the hospital bill was paid by medicare and Blue Shield.

"How many hundreds of these were called in over the country and how many thousands of dollars spent by medicare? It is one of the ways medicare is being milked, and I am incensed over it. When a car is called in, there is no expense to the customer. Why this?

"Every time one goes to the doctor, his charge is raised, and this last time a charge just for admitting me to the hospital and writing the orders was $90. Medicare allowed $75.

"Please refer this letter to the proper ones.

"Very truly yours, (Mrs. Louis) Madeline Garman."

Senator, that is my story, and I still cannot understand why medicare should be pay[illegible] for a pacemaker that failed.

Senator CHILES. Thank you very much, Mrs. Garman.

After you first wrote me, we asked you to send us copies of your hospital and doctor bills for the two pacemaker operations, and you did, and we have them here for the record.[1] It appears from these bills that your first pacemaker implant, which was in January of 1979, cost about $6,900, and most of that was for the hospital, some $5,400, and the pacemaker itself, including the leads, was billed at $2,960. That is correct, isn't it?

Mrs. GARMAN. Correct.

Senator CHILES. When that one was recalled, and you had a new pacemaker in May 1981, your bill showed that the total cost was about $5,300, and this time the pacemaker—and it is only the battery part—was billed at $3,900.

Mrs. GARMAN. Correct.

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[1] See appendix 1, item 1, page 105; and item 2, page 112.

Senator CHILES. So the second pacemaker, which did not include new leads, cost about $1,000 more than the first one, and as far as you know, medicare paid for all the bills both times, except for the deductible, the coinsurance, and $450 from Intermedics.

Mrs. GARMAN. Yes.

Senator CHILES. When you were given your first pacemaker you were told that it was guaranteed for how long?

Mrs. GARMAN. For 8 years.

Senator CHILES. And it was replaced 1½ years later?

Mrs. GARMAN. Yes.

Senator CHILES. I see. We know that many pacemaker companies have two features in their warranties. One is a replacement credit to cover the cost of the pacemaker that failed before the warranty ran out, just like you would have if you bought a new car. The second is the promise to pay unreimbursed medical expenses to help cover the cost of a second operation. In your case, it looks like you, or medicare, did not get any replacement credit. The whole cost of the second pacemaker was billed to medicare.

Mrs. GARMAN. Correct.

Senator CHILES. But you did get a check from Intermedics for the unrelated medical expenses, and how much was that check?

Mrs. GARMAN. $450.

Senator CHILES. We would like to have a copy of that letter for our records, if you can provide it.

[The letter referred to follows:]

11-485 O - 83 - 2

Intermedics Inc.

Friday, May 22, 1981

Ms. Madeline Garman
926 Whitfield Avenue
Sarasota, Florida 33580

Dear Ms. Garman:

On behalf of Intermedics, Inc. and our sales representative Mr. Phil Williams, may I express our appreciation to you for your cooperation in the matter of the placement of your Intermedics pulse generator.

Enclosed please find a check in the amount of $450.00 to cover those expenses not paid by your insurance.

Ms. Garman, please do not hesitate to call on us if we can be of any additional service to you. Again, thank you.

Sincerely,

Yvonne Gill

YVONNE GILL
Supervisor
Insurance and Claims

YG:psb

xc: Mr. Phil Williams

Enclosure: 1 check

P.O. Box 617, Freeport, Texas 77541 • Phone: (713) 233-8611 • Telex: 792503

INVOICE NO.	VOUCHER	DATE	GROSS AMOUNT	DISCOUNT	NET AMOUNT
Patient reimbursement			$450.00		$450.00

INTERMEDICS, INC.
P.O. BOX 617
FREEPORT, TEXAS 77541

VENDOR NO.	CHECK NO.	DATE	CHECK AMOUNT
69350	39204	5-22-81	$450.00

Senator CHILES. Now, Mrs. Garman, I am very glad you wrote to us, and I want to thank you for coming here. You have helped us understand a bad warranty situation with pacemakers. We do not know if a replacement credit was ever given to anyone for your second pacemaker, but we know that it was not credited to medicare. We can do something about that by better tracking of the pacemaker warranties and pacemaker performance and requiring some kind of a registry and reporting of pacemaker failures. We can also insist that the amounts that medicare pays for pacemakers be much more realistic and in line with costs.

And I hope that you will be able to see something happen very soon as a result of these hearings, and as a result of the matter that you brought to our attention.

Do you have anything else that you would like to say to our committee?

Senator HEINZ. Senator Chiles, there will be an opportunity for other members of the committee to question Mrs. Garman later. I just want to put on the record the fact that her case, involving the warranty, replacement, is by no means unique. In 1977, the Federal Trade Commission initiated an investigation of the medicare program, and it was kicked off by the complaint by one William Meadows, who received a bill—this is in fact the bill that he received. This bill totaled some $7,000. That was his first bill.[1]

Then, along came a few years later, the need to replace the pacemaker and, as you might expect, another bill was generated, this one a little shorter, but not a lot less.[2] This is $3,710 for the replacement of the pacemaker. Now, that pacemaker was well within the warranty period, as was yours. It was replaced, but none of the warranty was ever collected by medicare. It was all exactly as you described to us in your letter—once again, a real ripoff of the medicare system. And in this way, what we have is an example of product liability being passed on, not to the profession or to the manufacturer or whoever, but to medicare itself.

If you take that example, and you multiply it times the 150,000 people who will have pacemaker operations this year, leave aside

[1] See appendix 1, item 3, page 119.
[2] See appendix 1, item 4, page 129.

the 500,000 people who are on monitoring of one kind or another, of course, all reimbursed by medicare, and what you come up with is just a staggering amount of money, just on the warranty provision; some 30,000 of the 150,000 operations each year are just for replacement, and to my knowledge, medicare receives at best 5 percent of the money back from the warranty coverage that it could receive. That in itself is obviously millions of dollars.

Our next two witnesses requested that the committee issue to them friendly subpenas. Yesterday in executive session, the committee did meet, we did vote friendly subpenas so that these witnesses could testify freely and fully before this committee. That also, however, requires upon us the obligation that we swear our two witnesses in.

Do you swear the testimony you are about to give is the truth, the whole truth, and nothing but the truth?

Mr. WASLEY. Yes.

Mrs. ALDERMAN. Yes.

Senator HEINZ. Very well.

Mr. Wasley, would you please proceed?

Mr. WASLEY. Senators, my name is Greg Wasley. I am an attorney practicing in Tucson, Ariz. My partner, Leonard Scheff and I, represent eight individuals who have filed medical malpractice lawsuits against two cardiologists and a hospital for the unnecessary implantation of permanent heart pacemakers.

Each of our clients has been examined by expert cardiologists who have unequivocally determined that none of them ever required a pacemaker. During the course of our discovery in the lawsuits, we obtained the medical records of 24 patients who had pacemakers implanted during one 4-month period in 1979. Our expert cardiologists reviewed those records and concluded that of the 24 pacemaker implantations, 20 were unnecessary.

Our clients have been hospitalized for as long as 10 days at a time in connection with unnecessary patient procedures and associated testing. One of our clients has incurred medical expenses in excess of $50,000 for the implantation of two unnecessary pacemakers. Three of our clients are members of the same family: father, mother, and son.

Based on our experience in these cases, it is our recommendation, in order to limit the type of abuses we have seen, that medicare take the following steps: The American College of Cardiology should be requested to assemble a committee for the purpose of promulgating national standards for the implantation of pacemakers. Those standards should be reviewed from time to time by that committee. The medicare administration should adopt these standards by regulation and further require that any doctor implanting a pacemaker in a patient covered by medicare certify that the implantation is within these standards. If a physician implants a pacemaker that is not within these standards, he should be required to so notify the funding agency and state the reasons why he chooses to deviate from the standards.

The medicare administration should review all cases in which the physician has indicated that he has not complied with the standards. The administration should implement through PSRO—peer service review organization—random review of all pacemaker

implantations. Regulations should be adopted by the medicare administration to require the repayment of all medicare funds received by physicians and hospitals in those cases where it is determined that there is a material, unjustified deviation from the standards, or that there is a continued practice of deviating from the standards.

Furthermore, notification of this determination should be given to the patient. Any doctor who receives a stipend or other things of value, including training and travel, from any pacemaker company and who implants pacemakers in patients covered by medicare should be required to notify the medicare administration of the receipt of such compensation or other perks.

Based on our experience, we can assure you that even in the most outrageous cases of pacemaker abuse, almost any doctor accused of unnecessary pacemaker implantations will be able to assemble other doctors of the same ilk to testify that no malpractice was committed or, at most, an error in judgment was made.

Accordingly, we believe that efforts to obtain criminal convictions will not be productive. On the other hand, we believe that if our recommendations are followed, or even if the Government simply files a civil action against some of the more flagrant abusers of pacemaker technology, the rate of pacemaker implantations in this country will drop off sharply.

We have found that there is one symptom common to virtually all of the pacemaker abuse cases that we have seen that is used to justify the implantation of a pacemaker. That symptom is not found anywhere in the medical literature. That symptom is insurance coverage, whether through medicare or private insurance.

The strength of the abusing physician's belief in the miraculous effects of a pacemaker seems to be in direct proportion to the physician's ability to collect his fees. Undoubtedly, many hospitals who find themselves with empty beds also look the other way even when the number of pacemakers implanted by a particular physician becomes astoundingly large. We believe that until unscrupulous physicians and hospitals are made to understand that they will not be allowed to keep the profits realized from unjustified procedures, unnecessary pacemaker implantations will continue at the expense of the victims of those procedures and the American taxpayer.

Senator HEINZ. Mr. Wasley, thank you.

Mrs. Alderman.

Mr. WASLEY. Mrs. Alderman is one of our clients and could answer any specific questions that you might have about the problems she encountered.

Senator HEINZ. On behalf of the committee, then, Mrs. Alderman, let me ask you a few questions before we turn to general questions.

When did you receive a pacemaker, and what was the reason?

Mrs. ALDERMAN. In September 1978, I received the first pacemaker, and I received it because I just was not feeling too well. I had gone for a general checkup, and my doctor had suggested that I see a cardiologist, which I did. And through the course of events and being hospitalized for a HIS bundle test, an angiogram, I was told I needed a pacemaker.

Senator HEINZ. Now, after you received that pacemaker, did you feel better or worse?

Mrs. ALDERMAN. I did not feel any better.

Senator HEINZ. You did not feel any better?

Mrs. ALDERMAN. No.

Senator HEINZ. What caused you to get the pacemaker removed—when was your pacemaker removed, and how have you felt since?

Mrs. ALDERMAN. Well, I feel terrific now. It was removed in January of this year.

Senator HEINZ. And you have felt fine ever since?

Mrs. ALDERMAN. Yes, I have.

Senator HEINZ. So, whatever it was that ailed you several years ago had nothing to do with your heart, apparently?

Mrs. ALDERMAN. It had nothing to do with the pacemaker or my heart condition.

Senator HEINZ. Now, just one other question for Mr. Wasley. On page 3 of your testimony, you indicate that one of your clients accumulated medical expenses totaling $50,000. Who paid that bill?

Mr. WASLEY. That was a medicare patient.

Senator HEINZ. And that was paid by medicare, is that correct?

Mr. WASLEY. Yes, sir.

Senator HEINZ. Senator Chiles, do you have any questions for these witnesses?

Senator CHILES. No, I have none.

Senator HEINZ. And, following the "early bird" rule, Senator Pressler.

Senator PRESSLER. I would like to address the question, if I could, regarding the information. Do you feel that the physician in the hospital tried to avoid telling you how much medicare was being billed for your surgery and supportive services?

Mrs. GARMAN. I did not understand you. I am sorry.

Senator PRESSLER. Could you get information readily about the cost that medicare was being billed? You said you asked some questions about the costs, and so forth. Did you—what kind of response did you get when you asked questions about how much medicare was being billed?

Mrs. GARMAN. Well, they could not tell me; they would have to look it up.

Senator PRESSLER. And when they looked it up——

Mrs. GARMAN. They were too busy.

Senator PRESSLER. Did they tell you then?

Mrs. GARMAN. No; I have never heard from them.

Senator PRESSLER. So you were in a situation that you just did not know what was going on?

Mrs. GARMAN. Well, I knew they were not going to tell me, the same as when I asked how many he had transplanted the second time.

Senator PRESSLER. This is probably true of many patients. There is just no way you can question. I guess the terminology of all this is such that you probably would not know all of the terms. You asked the physician in the hospital about the bill. Did you ask how much was for surgery and supportive services?

Mrs. GARMAN. No, I did not, no. I asked no question about that. I understood, of course, suspecting that it was to be paid by Intermedics, that it would be paid at no cost to me; it would be transplanted at no cost to me whatever.

Senator PRESSLER. Were there other people at the same time who had pacemakers implanted, that were, in your opinion, also overcharged or inappropriate implanted?

Mrs. GARMAN. I had no idea. I did not ask them.

Senator PRESSLER. Thank you. That is all I have.

Senator HEINZ. Senator Cohen.

Senator COHEN. A couple of questions for Mrs. Alderman.

As I understand it, you felt bad, and you went to your regular physician, and he referred you to a cardiologist. The cardiologist said you needed a pacemaker. You had the pacemaker implanted, and then you continued to feel bad. What made you decide to have the pacemaker taken out?

Mrs. ALDERMAN. Well, I had had a great deal of difficulty with the pacemaker, and when I first had it implanted, inside of 15 days, I was back again, having it redone again. And I think it was about 17 days, and I was back again for the same operation. They replaced the battery at that time, so I had two pacemakers implanted within 6 weeks. Finally, I had read an article in the paper that there were some cases about malpractice of a pacemaker. I am a very active person, so I made an appointment with the University of Arizona, and I went to see a cardiologist there, and I had a checkup, and he said he did not think that I needed one, and at the time, he turned the pacemaker down as low as it would go. I functioned for about 6 months like that, and then finally, I went back and I said,"Let's take it out, because the thing is really uncomfortable, and it hurts all the time." So he said, "Fine, we'll take it out."

Senator COHEN. Now, that $50,000 charge, was that for the two operations?

Mrs. ALDERMAN. My total expenses came to about $30,000. There was another party that had $50,000. Yes. That was for the three operations, and then, of course, the last operation. It was all paid for by Metropolitan Insurance Co.

Senator COHEN. That is all I have.

Senator HEINZ. Senator Grassley.

Senator GRASSLEY. Mr. Chairman, I do not have any questions.

Senator HEINZ. Senator Pryor.

Senator PRYOR. Two quick questions, Mr. Chairman, for any member of the panel. I have heard that it takes only about 30 minutes to implant a pacemaker under today's procedure. Is this generally assumed to be correct? Mr. Wasley, maybe you could answer.

Mr. WASLEY. Senator Pryor, it usually depends on the cardiovascular surgeon, or the surgeon. We have seen some cases where it has taken them up to 1½ to 2 hours. I believe Mrs. Alderman underwent a procedure where she suffered a great deal of pain.

Senator PRYOR. Mrs. Garman, did you want to respond to this?

Mrs. GARMAN. It only took my surgeon 30 minutes.

Senator PRYOR. Thirty minutes for your implant?

Mrs. GARMAN. The first implant may have been a little longer, but not a whole lot longer. That is when they have to place the

wires into the heart. That takes a little longer. But this time, the second time, it was only the pacemaker that was implanted, you see, and I was in there about 30 minutes.

Senator PRYOR. Now, also, as I understand you, Mr. Wasley, and you have done a lot of work in this field, and perhaps I should address this to a physician shortly, but let me ask this question, is it true that today, under the medicare reimbursement formula that the reimbursement schedule is based on the old procedure of installing a pacemaker, that is, opening the chest cavity and putting the pacemaker within the chest itself? Today, I understand—and I know nothing about the terminology—that there is a slit, basically, and the pacemaker is put sort of in a semipocket of fatty tissue—which is a much improved process over the old one—but the formula for reimbursement is still based, I understand, on the old procedure. Am I correct there?

Mr. WASLEY. I am not sure about that, Senator Pryor, as to the medicare formula, but I can tell you that usually the bill includes much more than just the surgery and the pacemaker. There is usually quite a bit of testing that is done beforehand.

Senator PRYOR. I see. Thank you very much.

Senator HEINZ. Very well. Senator Durenberger.

Senator DURENBERGER. No questions, Mr. Chairman.

Senator HEINZ. Senator Domenici.

Senator DOMENICI. Mr. Chairman, I just have a question either of the staff or one of the witnesses. You referred to the warranty situation. Do we have a copy of the warranty involved in the situation, or one that is general to the industry?

Senator HEINZ. The Chair does not have one in its possession at the moment. I am sure we can get one.

Senator DOMENICI. I would be interested in seeing if they have been ingenious enough to warranty and exclude medicare from the warranty. If they have not, it would seem to me there is a nice cause of action to recover all of that money for pacemaker replacements, and we ought to ask somebody to look into that.

Senator CHILES. I think our problem is going to be the way medicare even keeps the records. My understanding is that the way they keep the records, you are never going to be able to go back and really look at the situation and pull it out. That is going to be one of our problems.

Senator HEINZ. Senator Domenici, I am advised that your inquiry is very much on target, that the way the warranties are written, they only pay the unreimbursed cost. You and I both know what that means. That means medicare pays, and only after medicare pays to reimburse does the warranty apparently come into effect. That may not be typical of every warranty, but that is what I am advised is present in some.

Senator DOMENICI. I have no further questions.

Senator HEINZ. Senator Pressler.

Senator PRESSLER. Yes, in following that question, I might ask this of Mr. Wasley: Where has the liability fallen in court cases if one of these devices malfunctions and someone dies, or their health is permanently harmed? Are you aware of jury decisions, or who pays the damages, so to speak, if a court awards damages for a defective one, or for one that is improperly placed?

Mr. WASLEY. Well, Senator Pressler, our suits deal with misdiagnosis. I am not aware of any suits regarding defective pacemakers. That would probably come under product liability law, and it would probably fall on the manufacturer, the liability. As far as misdiagnosis, that falls on the physician and the hospital, which is our case.

Senator PRESSLER. And have there been lawsuits where there have been damages awarded in that area for misdiagnosis?

Mr. WASLEY. Actually, ours are—I believe we are breaking new ground.

Senator PRESSLER. So, there have not been. I mean, the point is, do people have to carry high insurance who manufacture and supply or install these devices?

Mr. WASLEY. Well, it comes under the physician's malpractice insurance and the hospital's malpractice insurance.

Senator PRESSLER. Thank you.

Senator HEINZ. I have one last question. Let me just ask this to any of the people at the table. Senator Pryor has, I think, described accurately enough the pacemaker operation. To your knowledge, has anybody suffered any kind of health setback?

Mr. WASLEY. Senator Heinz, basically all of our clients generally felt worse after they had the pacemakers put in.

Senator HEINZ. Is that true of you, Mrs. Alderman?

[Mrs. Alderman responded by nodding her head yes.]

Mr. WASLEY. And their lives were severely disrupted. They were unable to—as in Mrs. Alderman's case, she was unable to go back to work. We have several people like that. Of course, they are physically limited in their activities. And I think it is very disruptive.

Senator HEINZ. Mrs. Alderman, you apparently were a really healthy person who had a pacemaker put in. Would you tell us what your life was like as a result of that operation?

Mrs. ALDERMAN. Well, it was very limited, and I could not do the normal things that I usually do. My husband and I used to square dance a lot. I was unable to square dance. And of course, I was not able to follow through with my job, because the very fact that the lead wire at that time—I do not know how they do it now—but the lead wire, at the time, it is implanted underneath the collarbone and goes down into the bottom part of the heart muscle, and every time you raise your arm, it hurts. So you are not able to raise your arm or lift anything too heavy. And my family was very protective of me, "Don't do this, don't do that." And I am very active in sports, and I had to stop almost all of that, except maybe swimming.

Senator HEINZ. And that was an instance where there was certainly no medical complications. The doctors, in effect, judged your pacemaker transplant a success, and yet it was debilitating and limiting to you.

Mrs. ALDERMAN. Yes, it was, it most certainly was.

Senator HEINZ. When you realized that this year, probably 120,000 to 130,000 new pacemakers will be implanted, and if you accept the median estimate that some 30 percent of those, about a third, are unnecessary, roughly 40,000 of those, while it is true that 80,000 people are probably getting a pacemaker that is necessary, there are 40,000 of them who are having their lives seriously dis-

rupted and impaired, even if the surgery is a total and complete success—and you are an example of that.

Mrs. ALDERMAN. That is right.

Senator HEINZ. And I gather, Mr. Wasley, you know several other people who, as you have testified, are in the same boat?

Mr. WASLEY. Yes.

Senator HEINZ. Very well.

Senator Grassley, you had a question.

Senator GRASSLEY. Yes. Mrs. Garman, before you wrote the letter to your Senator, did you discuss your feelings about this whole problem with your medical doctor, and if you did, I am particularly interested in what his attitude was.

Mrs. GARMAN. No, I did not. I think Senator Chiles was in the area speaking at the time and that gave me the idea to write to him about it. My cardiologist, whom I have gone to for 30-some years, had tried everything to regulate my heart, and it did not work, and he said the only alternative was the pacemaker, and he evidently was right, because the next morning, I felt able and ready to go home.

Senator HEINZ. Senator Chiles.

Senator CHILES. So actually, in your case, the pacemaker was necessary?

Mrs. GARMAN. It was necessary. I would not be here without it.

Senator CHILES. And the pacemaker has helped you, so that is something that you very much needed.

Mrs. GARMAN. Yes.

Senator CHILES. The question is not, in your case, one of overutilization at all. The question is the charge and the fact of the warranty coming back. But I think it is important to note that, even where there is overutilization in a lot of instances, it is not the beneficiary's fault and it is not the recipient's fault, but it is something that we need to look at.

Senator GRASSLEY. The point I was just going to make is what was the doctor's reaction to the problem as she saw it, with the increased costs that she had and the fact that it had to be replaced, and all that, but she said she did not discuss that with him.

Senator HEINZ. Senator Chiles.

Senator CHILES. My understanding is that the doctor is the one, Mrs. Garman, who called you and told you that there were problems with this type of pacemaker.

Mrs. GARMAN. The surgeon had called my cardiologist, and he knew that he was my doctor, and asked him to get in touch with me. And he said, "Now"—as he always called me my first name; we are social friends, as well—"it will be of no cost to you, and you will be out in a few days."

Then, when I go into the surgeon's office to be examined, he also told me that, "This will be at no cost to you." He said, "In fact, I had one man tell me he made a little on it."

Senator CHILES. That is what the surgeon said, that they were having to replace all of this particular pacemaker that they had placed——

Mrs. GARMAN. That model had to be replaced.

Senator CHILES. And I think you said something about they first checked to find out the ones that they knew were defective.

Mrs. GARMAN. Yes.

Senator CHILES. Had you noticed any trouble that you were having with it at the time?

Mrs. GARMAN. Well, I was not feeling as well and could not do as much, but I did not know why.

Senator CHILES. And after it was replaced, you did feel better?

Mrs. GARMAN. Oh, yes. Within 24 hours, I was better. The heartbeat drops, and you just have not the strength and the breath to go on and do things.

Senator CHILES. So in reflection, you do know that there was some defect?

Mrs. GARMAN. Oh, I know it very well, and I have other heart problems that, of course, are not affected by the pacemaker.

Senator HEINZ. Senator Burdick, do you have questions?

Senator BURDICK. No questions, Mr. Chairman.

Senator HEINZ. Very well. I would like to thank our witnesses. Your contribitions have been extremely valuable. We appreciate the journeys you have made from Arizona and from Florida to be here.

Thank you very, very much.

[Material submitted by Mr. Wasley follows:]

HISTORY OF PACEMAKER LITIGATION IN TUCSON, ARIZONA

ATTORNEYS FOR PLAINTIFFS:
S. LEONARD SCHEFF and GREGORY G. WASLEY

BACKGROUND

WE REPRESENT EIGHT INDIVIDUALS WHO HAVE FILED MEDICAL MALPRACTICE LAW SUITS AGAINST JOSEPH ROGERS, D.O., SALVADORE J. DeVITO, D.O., AND TUCSON GENERAL HOSPITAL FOR THE UNNECESSARY IMPLANTATION OF PERMANENT HEART PACEMAKERS. THE BASIS OF THE SUITS AGAINST THE PHYSICIANS IS THAT THEY NEGLIGENTLY PERFORMED CERTAIN DIAGNOSTIC TESTS AND NEGLIGENTLY PRESCRIBED THE IMPLANTATION OF PERMANENT HEART PACEMAKERS, ALL OF WHICH WERE MEDICALLY UNJUSTIFIED. THE BASIS OF THE SUITS AGAINST THE HOSPITAL IS THAT IT FAILED TO REVIEW THE NATURE, QUALITY AND NECESSITY OF THE CARE PROVIDED IN ITS FACILITY.

THE INDIVIDUALS WHO HAVE FILED SUIT ARE: ELEANOR ZIEGLER, AGE 51; THELMA COTTRILL, AGE 64; SHIRELY MOREHEAD, AGE 62; RUTH CAREY, AGE 78; EDNA ALDERMAN, AGE 51; DOLORES BENCOMO, AGE 74; RAMON BENCOMO, AGE 41; AND INEZ BENCOMO, AGE 75. (DOLORES AND INEZ BENCOMO ARE THE MOTHER AND FATHER OF RAMON BENCOMO. UNNECESSARY PACEMAKERS WERE IMPLANTED IN EACH OF THE BENCOMOS.)

MRS. ZIEGLER WAS OUR FIRST CLIENT. SHE WAS REFERRED TO US BY DR. BRENDAN PHIBBS OF KINO COMMUNITY HOSPITAL IN TUCSON. AN AV SEQUENTIAL PACEMAKER HAD BEEN IMPLANTED IN MRS. ZIEGLER IN MAY, 1979, BY DRS. ROGERS AND DeVITO. IN MARCH, 1980, MRS. ZIEGLER SOUGHT MEDICAL ADVICE AT KINO COMMUNITY

HOSPITAL BECAUSE OF THE SEVERE MEDICAL PROBLEMS SHE HAD BEEN EXPERIENCING SINCE THE TIME THE PACEMAKER WAS IMPLANTED. MRS. ZIEGLER WAS EXAMINED AT KINO, AT WHICH TIME IT WAS DETERMINED THAT SHE NEVER REQUIRED A PACEMAKER. HER PACEMAKER WAS REMOVED AND SUIT WAS FILED IN JUNE, 1980. FOLLOWING A HEARING AT WHICH IT WAS DETERMINED THAT DRS. ROGERS AND DeVITO UNNECESSARILY IMPLANTED A PACEMAKER IN MRS. ZIEGLER, WE WERE CONTACTED BY THE OTHER SEVEN CLIENTS. THEY WERE ALERTED TO THE POSSIBILITY THAT THEIR PACEMAKERS WERE UNNECESSARY BY THE PUBLICITY GENERATED BY THE ZIEGLER CASE.

EACH OF OUR CLIENTS WAS EXAMINED BY EXPERT CARDIOLOGISTS WHO UNEQUIVOCABLY DETERMINED THAT NONE OF THEM EVER REQUIRED A PACEMAKER. MRS. COTTRILL, MRS. MOREHEAD, MR. RAMON BENCOMO AND MRS. ALDERMAN HAVE HAD THEIR PACEMAKERS SURGICALLY REMOVED. MRS. CAREY, MRS. BENCOMO AND MR. INEZ BENCOMO HAVE ELECTED NOT TO HAVE THEIR PACEMAKERS REMOVED BECAUSE OF THEIR RESPECTIVE AGES AND THE RISKS ASSOCIATED WITH ANOTHER SURGICAL PROCEDURE. HOWEVER, THEIR PACEMAKERS HAVE BEEN REPROGRAMMED SO THAT THEY DO NOT INTERFERE WITH NORMAL HEART FUNCTION.

DURING THE COURSE OF OUR DISCOVERY IN THE LAWSUITS, WE OBTAINED THE MEDICAL RECORDS OF 24 PATIENTS OF DRS. ROGERS AND DeVITO WHO HAD PACEMAKERS IMPLANTED DURING ONE FOUR-MONTH PERIOD IN 1979. OUR EXPERT CARDIOLOGIST REVIEWED THOSE RECORDS AND CONCLUDED THAT OF THE 24 PACEMAKER IMPLANTATIONS, 20 WERE UNNECESSARY.

PROBLEMS ASSOCIATED WITH PACEMAKER IMPLANTATIONS:

PACEMAKER IMPLANTATIONS CAUSE SUBSTANTIAL PAIN DURING THE SURGICAL PROCEDURE. PATIENTS HAVE BEEN HOSPITALIZED FOR AS LONG AS 10 DAYS AT A TIME IN CONNECTION WITH IMPLANTATION PROCEDURES AND ASSOCIATED TESTING. ONE OF OUR CLIENTS HAS INCURRED MEDICAL EXPENSES IN EXCESS OF $50,000 FOR THE IMPLANTATION OF UNNECESSARY PACEMAKERS!

ALL OF OUR CLIENTS INDICATED THAT THEY FELT WORSE AFTER THEIR PACEMAKERS WERE IMPLANTED. MOST OF THEM COMPLAINED OF EXTREME FATIGUE, NERVOUSNESS AND GENERAL PHYSICAL DISCOMFORT. IN SOME CASES, THE DISCOMFORT STEMMED FROM DRAMATIC INCREASES IN THEIR PACEMAKER RATES WHICH CAUSED CONSIDERABLY HIGHER THAN NORMAL RESTING HEART RATES. THE PHYSICAL WELL BEING OF EACH OF OUR CLIENTS IMPROVED DRAMATICALLY AFTER THE REMOVAL OR REPROGRAMMING OF THEIR PACEMAKERS.

THE UNNECESSARY IMPLANTATION OF PACEMAKERS HAS ALSO LEFT EMOTIONAL SCARS. BEING TOLD THAT ONE CANNOT LIVE WITHOUT A PACEMAKER HAS A TREMENDOUS PSYCHOLOGICAL IMPACT. EVEN THE INDIVIDUALS WHO HAVE HAD THEIR PACEMAKERS REMOVED HAVE A DIFFICULT TIME ACCEPTING THE FACT THAT THEY CAN LIVE WITHOUT A PACEMAKER.

MRS. SHIRLEY MOREHEAD WAS OPERATED ON FIVE SEPARATE TIMES BY DRS. ROGERS AND DeVITO. MRS. ALDERMAN WAS OPERATED ON THREE SEPARATE TIMES. THE PACEMAKERS WHICH WERE IMPLANTED OR REPOSITIONED IN THESE OPERATIONS WERE TOTALLY UNNECESSARY.

THE IMPLANTATION OF PACEMAKERS CAN HAVE A SUBSTANTIAL NEGATIVE IMPACT ON JOB PERFORMANCE AND EMPLOYMENT OPPORTUNITIES. PACEMAKERS ARE SUBJECT TO MECHANICAL AND ELECTRICAL INTERFERENCE. WE HAVE SEEN THAT EMPLOYERS TEND TO DISCRIMINATE (SOMETIMES WITH REASON, SOMETIMES WITHOUT) AGAINST PEOPLE WHO HAVE HAD PACEMAKERS IMPLANTED (EVEN AFTER REMOVAL).

MR. RAMON BENCOMO WAS PHYSICALLY UNABLE TO RETURN TO HIS JOB FOR APPROXIMATELY ONE YEAR AFTER HIS PACEMAKER WAS IMPLANTED. WHEN HE DID RETURN TO HIS FORMER PLACE OF EMPLOYMENT, HE WAS DEMOTED FROM TRUCK DRIVER TO A JANITORIAL POSITION BECAUSE HIS EMPLOYER WOULD NOT ALLOW HIM TO WORK IN A POTENTIALLY HAZARDOUS POSITION WITH A PACEMAKER. AFTER THE PACEMAKER WAS REMOVED, MR. BENCOMO HAD TO FOLLOW A UNION GRIEVANCE PROCEDURE TO RECOVER HIS PRIOR JOB. MRS. ZIEGLER AND MRS. ALDERMAN WERE UNABLE TO CONTINUE THEIR EMPLOYMENT AFTER THEIR PACEMAKERS WERE IMPLANTED. SINCE THEIR PACEMAKERS WERE REMOVED, THEY HAVE ALSO ENCOUNTERED EMPLOYER RELUCTANCE TO HIRE AN INDIVIDUAL WITH A MEDICAL HISTORY OF PACEMAKER IMPLANTATION.

RECOMMENDATIONS

BASED ON OUR EXPERIENCE IN THESE CASES, IT IS OUR RECOMMENDATION, IN ORDER TO LIMIT THE TYPE OF ABUSES WE HAVE SEEN, THAT MEDICARE TAKE THE FOLLOWING STEPS:

(A) THE AMERICAN COLLEGE OF CARDIOLOGY SHOULD BE REQUESTED TO ASSEMBLE A COMMITTEE FOR THE PURPOSE OF PROMULGATING NATIONAL STANDARDS FOR THE IMPLANTATION OF PACEMAKERS.

(B) THOSE STANDARDS SHOULD BE REVIEWED FROM TIME TO TIME BY THAT COMMITTEE.

(C) THE MEDICARE ADMINISTRATION SHOULD ADOPT THESE STANDARDS BY REGULATION AND FURTHER REQUIRE THAT ANY DOCTOR IMPLANTING A PACEMAKER IN A PATIENT COVERED BY MEDICARE CERTIFY THAT THE IMPLANTATION IS WITHIN THESE STANDARDS. IF A PHYSICIAN IMPLANTS A PACEMAKER THAT IS NOT WITHIN THESE STANDARDS, HE SHOULD BE REQUIRED TO SO NOTIFY THE FUNDING AGENCY AND STATE THE REASONS WHY HE CHOOSES TO DEVIATE FROM THE STANDARDS.

(D) THE MEDICARE ADMINISTRATION SHOULD REVIEW ALL CASES IN WHICH THE PHYSICIAN HAS INDICATED THAT HE HAS NOT COMPLIED WITH THE STANDARDS.

(E) THE ADMINISTRATION SHOULD IMPLEMENT, THROUGH P.S.R.O., RANDOM REVIEW OF ALL PACEMAKER IMPLANTATIONS.

(F) REGULATIONS SHOULD BE ADOPTED BY THE MEDICARE ADMINISTRATION TO REQUIRE THE REPAYMENT OF ALL MEDICARE FUNDS RECEIVED BY DOCTORS AND HOSPITALS IN THOSE CASES WHERE IT IS DETERMINED THAT THERE IS A MATERIAL, UNJUSTIFIED DEVIATION FROM THE STANDARDS

OR THAT THERE IS A CONTINUED PRACTICE OF DEVIATING FROM THE STANDARDS. FURTHERMORE, NOTIFICATION OF THIS DETERMINATION SHOULD BE GIVEN TO THE PATIENT.

(G) ANY DOCTOR WHO RECEIVES A STIPEND OR OTHER THINGS OF VALUE, INCLUDING TRAINING AND TRAVEL FROM ANY PACEMAKER COMPANY, AND WHO IMPLANTS PACEMAKERS IN PATIENTS COVERED BY MEDICARE SHOULD BE REQUIRED TO NOTIFY THE MEDICARE ADMINISTRATION OF THE RECEIPT OF SUCH COMPENSATION OR OTHER "PERKS".

BASED ON OUR EXPERIENCE, WE CAN ASSURE YOU THAT, EVEN IN THE MOST OUTRAGEOUS CASES OF PACEMAKER ABUSE, ALMOST ANY DOCTOR ACCUSED OF UNNECESSARY PACEMAKER IMPLANTATIONS WILL BE ABLE TO ASSEMBLE OTHER DOCTORS OF THE SAME ILK TO TESTIFY THAT NO MALPRACTICE WAS COMMITTED OR, AT MOST, AN ERROR IN JUDGMENT WAS MADE. ACCORDINGLY, WE BELIEVE THAT EFFORTS TO OBTAIN CRIMINAL CONVICTIONS WILL NOT BE PRODUCTIVE.

ON THE OTHER HAND, WE BELIEVE THAT IF OUR RECOMMENDATIONS ARE FOLLOWED, OR EVEN IF THE GOVERNMENT SIMPLY FILES A CIVIL ACTION AGAINST SOME OF THE MORE FLAGRANT ABUSERS OF PACEMAKER TECHNOLOGY, THE RATE OF PACEMAKER IMPLANTATIONS IN THIS COUNTRY WILL DROP OFF SHARPLY.

WE HAVE FOUND THAT THERE IS ONE SYMPTOM COMMON TO VIRTUALLY ALL OF THE PACEMAKER ABUSE CASES WE HAVE SEEN THAT IS USED TO JUSTIFY THE IMPLANTATION OF A PACEMAKER. THAT SYMPTOM IS NOT FOUND ANYWHERE IN THE MEDICAL LITERATURE. THAT SYMPTOM IS INSURANCE COVERAGE, WHETHER THROUGH MEDICARE OR PRIVATE INSURANCE.

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THE STRENGTH OF THE ABUSING PHYSICIAN'S BELIEF IN THE MIRACULOUS EFFECTS OF A PACEMAKER SEEMS TO BE IN DIRECT PROPORTION TO THE PHYSICIAN'S ABILITY TO COLLECT HIS FEES. UNDOUBTEDLY, MANY HOSPITALS WHO FIND THEMSELVERS WITH EMPTY BEDS ALSO LOOK THE OTHER WAY EVEN WHEN THE NUMBER OF PACEMAKERS IMPLANTED BY A PARTICULAR PHYSICIAN BECOMES ASTOUNDINGLY LARGE. WE BELIEVE THAT UNTIL UNSCRUPULOUS PHYSICIANS AND HOSPITALS ARE MADE TO UNDERSTAND THAT THEY WILL NOT BE ALLOWED TO KEEP THE PROFITS REALIZED FROM UNJUSTIFIED PROCEDURES, UNNECESSARY PACEMAKER IMPLANTATIONS WILL CONTINUE, AT THE EXPENSE OF THE VICTIMS OF THOSE PROCEDURES AND THE AMERICAN TAXPAYER.

Senator HEINZ. Our next panel includes Howard Hofferman and J. Richard Stanley. While they are coming forward, I would only make the following observation on what we just heard from our two previous witnesses.

On the one hand, we have heard about procedures that were unnecessary. Some 80,000 estimated such procedures were apparently necessary and helpful last year; some 40,000 were not. In addition to that, there were some 30,000 who received replacements. And one question, given the warranty situation, that was brought to our attention by Senator Chiles' constituent is the extent to which those replacements in effect were necessary and proper, and the extent to which medicare was in fact reimbursed.

I would like to first swear our two witnesses in. They both requested and were granted yesterday, by unanimous consent of the committee, friendly subpenas.

So, Mr. Hofferman and Mr. Stanley, do you swear that the testimony you are about to give here is the truth, the whole truth, and nothing but the truth?

Mr. HOFFERMAN. I do.

Mr. STANLEY. I do.

Senator HEINZ. Gentlemen, thank you very much.

Let me ask Mr. Hofferman to be our leadoff witness.

PANEL NO. 2. PACEMAKER REPRESENTATIVES

STATEMENTS OF HOWARD F. HOFFERMAN, DENVER, COLO., AND J. RICHARD STANLEY, HOUSTON, TEX.

Mr. HOFFERMAN. Good morning, Mr. Chairman, members of the committee, and ladies and gentlemen.

My name is Howard Hofferman. I worked for 21 years in the general area of medical and pharmaceutical sales. For the last 1½ years of that experience, I worked as the national sales director

and director of sales and marketing administration for a major pacemaker manufacturer.

I am here today at your request to provide you with whatever information you may find helpful in your inquiry into the practices in the pacemaker industry. While in my opinion, the company I worked for, Telectronics, is perhaps one of the most ethical in the industry, the industry itself is replete with abuses. In all of my 20 years' experience in the medical sales field, I have never seen a business so dirty, so immensely profitable, and so absent normal competitive price controls as this one.

I am no longer associated with the pacemaker industry.

Currently, I am the president of my own manufacturing company, one that is not related to the medical field.

When your committee investigators first contacted me nearly 1 year ago, I agreed with them that it would take a congressional investigation to clean up this industry. I am fully prepared to cooperate with the committee in any way that they deem necessary.

Senator HEINZ. Mr. Hofferman, to put the facts of your views on the record, would you please describe the work positions you held prior to entering the pacemaker industry?

Mr. HOFFERMAN. Yes, sir. I was a pharmaceutical salesman for Alcon Laboratories in 1959 through 1962. I then was a pharmaceutical salesman for Hoffman-La Roche Laboratories for 9 years. In 1970, I was promoted to the position of regional sales manager for Roche Medical Electronics, another division of Hoffman-La Roche. I was with Hoffman-La Roche organization for a total of 14 years. In 1975, I was recruited by Litton Industries and went to work as eastern regional sales manager for Litton Microwave, a division of their Consumer Products Group. Two years later, they asked me to move into Litton Medical Electronics, which was having some problems, and I became the assistant to the vice president of Litton Medical. While at Litton Medical, I was recruited by Telectronics, in the end of 1978, and went to work for Telectronics as director of sales on January 1, 1979.

Senator HEINZ. So you were recruited by Telectronics. Would you please describe briefly the position you held in the pacemaker industry, what your general duties were, and the kinds of individuals who reported to you?

Mr. HOFFERMAN. I was responsible for the sales department. My duties included making up the sales budget, working with the director of marketing to determine the marketing plans, working with other people in the company in terms of both marketing and what pacemakers were necessary, what changes needed to be made. I had three regional sales managers who reported to me who were responsible for the sales force. When I began working for Telectronics, they had a mixed sales force of both direct salesmen, that is, salaried salespeople, men and women, and they had an independent rep organization. The policy of the company at the time, as provided to me by the general manager, Bill Fay, was that he felt and the company felt that we would be better off with a non-direct rep force, that is, individuals.

The first job that I had at Telectronics was to change over the sales force, make changes in salespeople from direct salespeople to independent reps, and recruit new reps.

Senator HEINZ. Without getting specific, did your move to the pacemaker industry include a significant increase in compensation?

Mr. HOFFERMAN. Yes, it did.

Senator HEINZ. In your opening remarks, you mentioned that normal competitive price controls are absent in this industry. Would you explain how medicare and other third-party reimbursement contributes to that condition?

Mr. HOFFERMAN. It seemed that, except for some isolated instances in certain hospitals, that the decision as to what pacemaker was implanted was made by the physician. The companies were not too concerned about the selling price of their pacemaker, because if a physician chose one pacer over another, they really did not look into the pricing structure.

The general thought was that third party was going to pay. The third party was usually medicare because your average pacemaker patient is, I think, somewhere in the sixties, and they are probably going to be on medicare anyway.

Senator HEINZ. Are you saying that with a very few exceptions, the price of the pacemaker involved was rarely or never considered in the purchase decision?

Mr. HOFFERMAN. I think that in most instances, it was not, from discussions that we had. However, normal procedure and competition would dictate that comparing apples to apples, one company's pacemaker to another, would generally fall within the same price range.

Senator HEINZ. Now, having been a manufacturer's rep, can you tell us the difference between the manufacturer's cost of a pacemaker and the price for which it was ultimately sold?

Mr. HOFFERMAN. It is a little difficult to do. The best way that I can explain it is that you have, first, a manufacturing cost. In our company, the marketing department then purchased that pacemaker from our manufacturing facility. In some instances, we would see a cost on a pacemaker, let us say, of $800; we might purchase it from the manufacturing division for $1,500, which would give them a gross profit, not necessarily a big net profit. We then determined what price we were going to sell it for, based on the normal factors involved in marketing, sales, and overhead. By the time we got done with it, at least in our company, in Telectronics, I believe at the time, our most expensive pacemaker was about $2,500, which was probably at the lower end of most pacemakers in terms of, again, comparing apples to apples.

Senator HEINZ. So your markup was around 60, 80 percent, your sales markup?

Mr. HOFFERMAN. Somewhere in that range, yes.

Senator HEINZ. On top of the price you were charged from the manufacturing subsidiary, which covered all costs, including profit?

Mr. HOFFERMAN. I believe so, sir.

Senator HEINZ. Is it a fair statement to say that a majority of the differences between manufacturing and retail price consisted of marketing expense and compensation to salespeople?

Mr. HOFFERMAN. Yes, sir.

Senator HEINZ. How important in the purchase decision is the doctor-salesperson relationship in the pacemaker industry?

Mr. HOFFERMAN. Generally, very important.

Senator HEINZ. From your knowledge, can you tell us how the sales climate in the pacemaker industry changed between, say, 1974 and the way it operates currently, today?

Mr. HOFFERMAN. Senator, during that period of time until I went to work for Telectronics in 1979, I was not directly or even indirectly involved with the pacemaker industry, and any knowledge that I have would be based merely on information given to me when I went to work for Telectronics.

Senator HEINZ. Well, what is your general understanding of the changes?

Mr. HOFFERMAN. The general understanding that I had is that there were basically two or three major pacemaker companies, and some salespeople from one company started another company and developed a new method of promotion of selling pacemakers. Up to that point in time, I believe that all of the sales representatives were direct salesmen, that is, they were paid a salary, possibly a commission or a bonus arrangement, depending on the company. When this new company was formed, they went to, from what I understand, a straight commission. The commission was quite large. There were many, many pacemakers sold, as you indicated, 130,000 of them in the United States alone, and your profits just continue to multiply.

Senator HEINZ. Is it true that other companies were forced to make the same kind of changes?

Mr. HOFFERMAN. A number of them did, from what I understand, yes, sir.

Senator HEINZ. Now, did one type of relationship tend to be associated with a more abusive kind of market practice than some others?

Mr. HOFFERMAN. I am not sure I understand that question, Senator.

Senator HEINZ. Well, what I mean is the kind of employment relationship, where on the one hand there was a very independent kind of salesman, as opposed to a direct salesman.

Mr. HOFFERMAN. There certainly is a difference between the two. When I went to work for Telectronics, we had a combination of the two of them, as I mentioned earlier, and what we indicated to our salespeople is that their opportunities for making more money certainly fell in the realm of them being independent reps. You also have a lot less control over an independent rep than you do over someone whose salary, insurance, car, and so on, you are paying.

Senator HEINZ. So you might say an independent rep is a good deal freer to wheel and deal?

Mr. HOFFERMAN. I would certainly think so.

Senator HEINZ. I want to get a little more specific as to the specific sales practices. At the firm for which you worked, what kind of sales commissions were paid to sales representatives; what other kinds of compensation were received?

Mr. HOFFERMAN. Our commissions changed a number of times while I was there. I believe initially, it was a 20-percent commission. However, because of higher commissions being offered by other pacemaker companies and the fact that we felt we would lose a number of our better salespeople, after a meeting with a number

of salespeople, we compromised at a commission that I believe was 23 percent, plus they got another 2 percent if they met their sales goals or quota. There was also another 1 percent that we used to buy little giveaways, that the salesmen would actually pay for. In our company, they consisted of koala bears that we probably did not pay more than 50, 60 cents or something like that.

Senator HEINZ. Any other kinds of compensation?

Mr. HOFFERMAN. There was no other direct compensation.

Senator HEINZ. While you were working at the pacemaker company, could you just answer yes or no to as to whether or not you or the company ever offered any of the following sales inducements; for example, take doctors on ski weekends?

Mr. HOFFERMAN. Yes, sir.

Senator HEINZ. Do you want to describe that?

Mr. HOFFERMAN. I never attended one of these. However, the company felt that we were in a prime location, being in Denver, and it would give us an opportunity to take small numbers of doctors to some place where they could sit down with them in a more informal atmosphere and try and promote the Telectronics pacemaker, based on the features and benefits of our particular pacemaker.

Senator HEINZ. What would be the normal day's schedule?

Mr. HOFFERMAN. Again, as I said, I did not attend any of these. I am not sure what the schedule was, but there was a period of time set aside each day for lectures, and what they tried to do is to either bring in a pacemaker expert physician, someone who really was well-respected in the pacemaker industry, or Dr. Collin Sutton, who was vice president of the company, and a Ph. D., not an M.D., would lecture to them.

Senator HEINZ. Would you say that most of the time was spent skiing or attending lectures?

Mr. HOFFERMAN. From what I understand, most of the time was spent skiing.

Senator HEINZ. Now, how about whether or not payments of $150 or $200 for new clinical evaluation, new product clinical evaluations of the sales promotion—have you ever seen that?

Mr. HOFFERMAN. Yes, sir. I was involved with our director of marketing services in setting those up. They were required by the FDA in order for us to get release of our product.

Senator HEINZ. The clinical evaluations were required?

Mr. HOFFERMAN. Yes, sir.

Senator HEINZ. What about the payment of $150 or $200.

Mr. HOFFERMAN. It was very difficult to get a physician to implant a new pacemaker that has not been fully tested in humans and fill out pages of information, maybe four, five, or more pages long, and the only way you are going to get them to do it is with some kind of compensation.

Senator HEINZ. Is it true that if the doctor implanted 60 pacemakers, he could get a trip to Australia paid for, and if he implanted 80, he could take his wife?

Mr. HOFFERMAN. If he asked us.

Senator HEINZ. If he asked you. So the answer is yes.

Mr. HOFFERMAN. Yes.

Senator HEINZ. Is it true that offering expensive equipment free to doctors as a condition of buying pacemakers was a customary practice?

Mr. HOFFERMAN. It depended on the situation. We would much prefer in Telectronics to sell the equipment. If we didn't, we would lend them equipment. We never gave anything away. We considered it always the property of Telectronics.

Senator HEINZ. Do you know of people in the industry who were not so scrupulous and may have given the equipment away?

Mr. HOFFERMAN. Since I was not there, it would be very difficult for me to answer that properly.

Senator HEINZ. What can you tell us about the experiences you had with two separate requests from physicians, one for a gold watch and the other for bags of money?

Mr. HOFFERMAN. We got a call from a salesman in the Northeast part of the United States one day. He had a physician who would implant our pacemaker if we supplied him with a particular gold watch. I believe the watch was worth $8,000 or $9,000. Gold was pretty high at the time, and it was 18-karat. I told the salesman that I would have to get back to him. I proceeded to talk to Dr. Collin Sutton and discuss it with him, and his feeling was the same as mine, and I will not repeat what he said, but we told the salesman to tell the doctor to go implant somebody else's pacemaker.

The other instance was a doctor from the New York area who called me on the telephone and said that he was hot to start implanting Telectronics pacemakers. He wanted, as I recall, $200 per pacemaker delivered to him and $200 per pacemaker in a paper bag, quote-unquote, "delivered to his father in Brooklyn."

Senator DURENBERGER. Like G. Gordon Liddy.

Senator HEINZ. How did you handle that request?

Mr. HOFFERMAN. Well, again, I went to Dr. Collin Sutton, and when the two of us stopped laughing, we called the salesman and informed the salesman, and the salesman said, "Listen, do you want to do it?" and I said, "No, I have no intentions of doing it. I just want you to be aware of what has happened." And the salesman, who was a very honest individual, said to me, "Boy, that's one I won't touch with a 10-foot pole."

Senator HEINZ. What do you suppose that salesman would have done if he had been told, "Go ahead and do it"?

Mr. HOFFERMAN. This particular salesman, I think he would have been so nervous that he would probably not do it or quit.

Senator HEINZ. Would every salesman in the industry feel that way?

Mr. HOFFERMAN. That is a difficult thing to answer. I know I would not do it.

Senator HEINZ. Have you, based on your 20 years experience in this industry, and in the medical sales industry generally, ever seen anything comparable to the kinds of sales inducements to doctors offered in this industry?

Mr. HOFFERMAN. No, sir, I have not.

Senator HEINZ. I thank you for your testimony.

I apologize to members of the committee. These witnesses are not exactly anxious to be here today. It is not easy to testify on what one may have been professionally involved with or seen. Since they

do not have prepared statements, it is necessary for the Chair to ask these questions to elicit the information for the record.

I want to call on J. Richard Stanley, who is accompanied by some people.

Mr. Stanley, who are you accompanied by?

Mr. STANLEY. Rod Petula is my attorney, on my left, and he is here this morning due to a past litigation that I had with a pacemaker company. And my wife on my right, Linda Stanley, to help recall dates if necessary.

Senator HEINZ. We welcome you all to the committee. I understand, Mr. Stanley, you worked for four pacemaker manufacturers from 1975 to 1980, and that you were the marketing director for three of these firms; is that correct?

Mr. STANLEY. That is correct.

Senator HEINZ. I also understand you have met with staff previously, and you have had an opportunity to review our report on waste, fraud, and abuse in the pacemaker industry—is that correct?

Mr. STANLEY. Very briefly last night, yes, sir.

Senator HEINZ. On page 42 of that report, there is a discussion of kickbacks, rebates, and other improper inducements offered to do business in the industry. At the top of page 43, "Direct cash payments to pacemaker implanting physicians are identified as one kickback mechanism."

Are you aware of payments of this nature?

Mr. STANLEY. With regard to my experience in the four companies, there were payments made for consulting programs or for clinical evaluation programs, if you will. Again, what Howard Hofferman said about the requirements, inducements, if you will, to solicit the cooperation of the doctors in trying out a new pacemaker, which required more closely following the patient because the pacemaker had not been tried and proven yet—there were those kinds of payments made.

Senator HEINZ. Do you recall seeing at one of your previous places of employment the list of doctors receiving direct rebates for implanting the company's pacemakers?

Mr. STANLEY. Yes, sir.

Senator HEINZ. How long was the list? Was it a full page, a half-page?

Mr. STANLEY. Somewhere between one-half and two-thirds of an 8½-by-11-size page.

Senator HEINZ. Are you aware of situations where kickbacks were disguised as payments for clinical investigations?

Mr. STANLEY. I would not use the word "disguised," if I can elaborate. In some cases, I understand, although it did not fall within the marketing department, some doctors did not fill out or complete the necessary information, but received the clinical evaluation amounts for implanting the pacemakers.

Senator HEINZ. So in effect, they did not perform what was required of them, and yet they still received the payments; is that right?

Mr. STANLEY. Yes, Senator.

Senator HEINZ. To your knowledge, was any inexpensive or cheap stock ever used as an inducement?

Mr. STANLEY. Yes.

Senator HEINZ. Are you aware of situations where stock options were offered to physicians to buy a particular brand of pacemaker?

Mr. STANLEY. Yes, I am.

Senator HEINZ. To your knowledge, were rebates ever disguised in any of the four firms where you worked as payments for unreimbursed medical expenses?

Mr. STANLEY. Could you please elaborate on that?

Senator HEINZ. To your knowledge, were rebates ever disguised in any of the four firms where you worked as payments for "unreimbursed medical expenses"?

Mr. STANLEY. Yes.

Senator HEINZ. Are you aware of situations where implanting pacemaker physicians were made silent partners in pacemaker sales and distribution companies?

Mr. STANLEY. Yes.

Senator HEINZ. To your knowledge, was business equipment offered as an inducement to do business?

Mr. STANLEY. Yes.

Senator HEINZ. Was that done frequently?

Mr. STANLEY. Yes.

Senator HEINZ. Are you aware of situations where implanting physicians were taken on ski trips, flown to the Bahamas, Australia, and other places?

Mr. STANLEY. Yes.

Senator HEINZ. Were you responsible for organizing the reception mentioned on page 45 of the report, where the Dallas cheerleaders were hired as hosts?

Mr. STANLEY. Yes.

Senator HEINZ. I have before me a brochure, promising a flawless opal, the same size as Senator Pryor's pacemaker, from Australia. This brochure was sent to every physician attending a reception in 1978. Did you attend that reception, did you arrange that reception, and was it well attended?

Mr. STANLEY. Yes, I did, and yes, it was well attended.

Senator HEINZ. It is true that every physician who attended also got a small opal, as well?

Mr. STANLEY. That is correct.

Senator COHEN. Did they cost about the same price as the koala bear, about 60 cents? [Laughter.]

Senator HEINZ. What is the relation of the cost of manufacturing a pacemaker to its list price?

Mr. STANLEY. Approximately 5 or 6 years ago, the rule of thumb was 4 to 1.

Senator HEINZ. How well are pacemaker salesmen in general paid?

Mr. STANLEY. As independent representatives, very well; as a direct representative of a manufacturer, not as well.

Senator HEINZ. Do you know of any salesmen who made in excess of $1 million a year?

Mr. STANLEY. As a sales organization or rep group, yes.

Senator HEINZ. In light of what you said, would you agree with the committee's assessment, as evidenced by our report, that the

kickbacks, bribes, rebates, and other improper inducements are pervasive in the selling of pacemakers?

Mr. STANLEY. Yes.

Senator HEINZ. Mr. Stanley, I thank you for putting this information on the record.

Let me defer to Senator Chiles for any questions.

Senator CHILES. The so-called clinical evaluation that doctors would fill out and that they would be paid a fee for, were they ever used by the company?

Mr. STANLEY. Most definitely, yes.

Senator CHILES. They were used?

Mr. STANLEY. Yes, sir.

Senator CHILES. But sometimes you paid for them whether they were filled out or not?

Mr. STANLEY. Specifically, I cannot recall details on it, but as a general rule, if a physician signed up for the duration of a clinical evaluation program, it was in good faith that for each pacemaker put in, the moneys would be forwarded, realizing that the paperwork that he would complete took a greater length of time because it was over a period of time, not only the initial implant, but in the followup of that new pacemaker with that patient.

Senator CHILES. Those are all the questions I have.

Senator PRESSLER. I have a brief question. What if a salesman in this industry were completely honest and did not participate in any of these practices; what would happen to him?

Mr. STANLEY. Please repeat that. I am not sure I understand.

Senator PRESSLER. What if a salesman were completely honest and did not participate in any of the practices described—he just went out and sold these pacemakers without any offers or additional inducements. Would he sell them?

Mr. STANLEY. I believe he would, yes. There are some, I believe, today, doing very well, to my knowledge, not partaking in those kinds of practices.

Senator PRESSLER. Do you know what kind of product liability insurance your company carried on these devices?

Mr. STANLEY. No, sir, I do not.

Senator PRESSLER. Those are the only questions I have.

Senator Cohen.

Senator COHEN. Mr. Hofferman, what was it that changed your mind so that your conscience outweighed the compensation? What was it that did it? Was it the watch?

Mr. HOFFERMAN. I do not understand.

Senator COHEN. You said in your opening statement that this was one of the most dirty businesses that you had ever encountered, so dirty and so highly profitable that you, I assume, became rather disgusted in this field and decided to get out.

Mr. HOFFERMAN. No, sir.

Senator COHEN. Then I misunderstood what you said.

Mr. HOFFERMAN. I left Telectronics for other reasons. They were mutual, between myself and the president of the company. I believe now, as I did then, that the atmosphere at Telectronics, in reference to some of the things that have gone on in the rest of the industry, were very clean, and we were able to generally live with them.

As I stated when the doctor requested a gold watch, I would like to quote what Dr. Sutton said, but I do not think it would be proper.

Senator COHEN. Well, I do not really want to go into what he said or did not say, but the fact of the matter is, I am not so much concerned about the doctors, but rather, the Telectronics policy. Once you shifted from going from direct representatives to independent sales representatives, what you did in essence was adopt a policy of saying, "Go out there and turn these men and women loose so that they can feed their appetites by going after this business." That was a policy that was instituted by you, or by Telectronics, wasn't it?

Mr. HOFFERMAN. The policy was instituted by Telectronics to go to an independent rep force.

Senator COHEN. And the purpose was that if you just pay people and put them on a salary, they are not going to be that aggressive in going out and promoting a product which is essentially identical to a number of others that are produced by other manufacturers. What you have to have is a lot of incentive, and the incentive is compensation. And if you offer them 25-percent commission, they are going to be a lot more ambitious out in the marketplace, aren't they?

Mr. HOFFERMAN. Yes, sir, they are.

Senator COHEN. And as a matter of fact, being so ambitious, they are going to go out and make certain representations to doctors. That was not unanticipated, was it?

Mr. HOFFERMAN. It was certainly not condoned by the company. We tried to police the situation as best we could.

Senator COHEN. Do you find that practice of offering special benefits to be inconsistent with other facets of the business world?

Mr. HOFFERMAN. I do not know if it is different than other facets of the business world, but I can tell you that it is completely opposite of the rest of the medical industry.

Senator COHEN. What, the pacemaker division?

Mr. HOFFERMAN. Yes, sir.

Senator COHEN. So, in all of your 20 years of experience, you never found a situation where, in the manufacture of other medical supplies, that these sorts of inducements or bonuses were offered to a physician to buy certain products?

Mr. HOFFERMAN. Senator Cohen, in all my years, I think the most expensive gift I ever gave away, when one-quarter-of-a-million-dollar intensive care unit was purchased by a hospital in Cleveland, Ohio, was a Mr. Coffee machine that cost $20 at K-Mart, and I gave that to the ICU. Other than that, you took a doctor to lunch, and generally, you ate in the hospital cafeteria.

Senator COHEN. Then, tell me why you became dissatisfied with this particular division. The watch was one case. You had trips, you had Las Vegas showgirls, or cheerleaders in Dallas, but what was it that became so unpalatable to you that you felt that this was a division or an industry you felt you should not stay with any longer?

Mr. HOFFERMAN. That is a difficult question for me to answer, because at the time, I really did not give that very much thought. I left the industry, or left pacemaking, for a totally different reason,

and decided that when I did leave that like many people, I wanted to be an entrepreneur and went into my own business, my own manufacturing company.

Senator COHEN. Are you saying that the general industry itself, Telectronics, was only representative of a general practice that was endemic throughout the industry of pacemakers?

Mr. HOFFERMAN. Again, I cannot say that. There were companies in the pacemaker industry that had, during the 1½ years that I was there, almost an unblemished reputation; you did not hear of any of the things going on. There were other companies that it seemed to be common practice to do all types of things. It did not necessarily mean what position the company was in terms of sales.

Senator COHEN. What was the guideline—were you the one who decided—what was the guideline in terms of physicians who requested trips with their wives, or gold watches?

Mr. HOFFERMAN. We did not give any of the gold watches out.

Senator COHEN. I understand that. But in other words, a trip was OK, but a watch is too much. What was the dividing line——

Mr. HOFFERMAN. OK, let me explain the purpose of the trip to Australia. Prior to my coming to Telectronics, they had actually invited a large number of physicians to Australia and, I believe, chartered an airplane and took them there, along with the salesmen. The problem with our company was, as an Australia-controlled company—although I understand we were an American corporation—most of our research was done in Australia, and it was very difficult to get the people in Australia to understand both the medical and the marketing needs of the American physician or the American marketplace. Therefore, we looked at this arrangement of sending a physician to Australia as a method by which we could get that physician there, have him spend a day or two with the people at Telectronics, and they can get some pretty indepth information from them.

We never, to my knowledge, paid for a trip just for the sake of a trip.

Senator COHEN. How about to Denver?

Mr. HOFFERMAN. If a physician wanted to come to Denver to visit us, we certainly would pick up his air fare.

Senator COHEN. And skiing trips?

Mr. HOFFERMAN. The skiing trips were by invitation, which the sales department was entitled to so many trips, or so many physicians they could bring up at any one time.

Senator COHEN. But that was legitimate, as far as you were concerned at that time, as an inducement to have the physicians become better informed about that particular pacemaker?

Mr. HOFFERMAN. I was not directly involved with that program.

Senator COHEN. No. All I am saying is that this was within acceptable norms.

Mr. HOFFERMAN. Yes, sir.

Senator COHEN. That is all I have.

Senator HEINZ. Senator Pryor.

Senator PRYOR. I have become enamored, looking at that opal.

Senator HEINZ. The Dallas cheerleaders went with it, too, Senator.

Senator PRYOR. Well, they have got class, that is, they do know how to attract a crowd.

I have two or three questions, and one is—I am asking this as an overall question about the industry as a whole—is it true that salespeople who sell pacemakers actually assist in the operating room?

Mr. HOFFERMAN. Yes, sir.

Senator PRYOR. In what capacity do they assist in the operating room?

Mr. HOFFERMAN. The only capacity that they should be involved in the operating room is to generally run the electronic equipment involved with the insertion of the pacemaker, and read the values to the physician.

Senator PRYOR. And what training do they have before they go into that operating room?

Mr. HOFFERMAN. It depends. Initially, the original pacemaker salesmen, to my knowledge, that were hired by Medtronics—I could be wrong in this—but the people that I knew who worked for Medtronics in the beginning, were generally cath lab technicians. These are people who are very well trained in the cath lab and have good medical training but are obviously not physicians.

Senator PRYOR. Do they put on an operating gown, and scrub, and so forth?

Mr. HOFFERMAN. They probably did not scrub. "Scrub" means that you actually scrub your hands and put on a pair of gloves. But they were sterile in the fact that they wore sterile gowns, a cap, and a mask.

Senator PRYOR. Do you know of any instance—I should also address this to Mr. Stanley—where a salesperson who sold pacemakers actually physically assisted the physician in implanting the pacemaker?

Mr. STANLEY. Not to my knowledge.

Mr. HOFFERMAN. Not to mine, either.

Senator PRYOR. What percentage of the implantation cases would a salesperson be physically present in the operating room procedures?

Mr. STANLEY. A good portion of them.

Senator PRYOR. Over 50 percent?

Mr. HOFFERMAN. Probably, yes.

Senator PRYOR. I think staff has estimated probably in the 1970's, 75 percent. Do you think that would be accurate or near accurate?

Mr. HOFFERMAN. It sounds accurate, Senator.

Senator PRYOR. We talked about the commission basis and how salesmen are compensated. What would you say today would be the average salary, plus commission, of a full-time salesperson who sold pacemakers?

Mr. HOFFERMAN. At Telectronics when I went to work for them, I believe that probably the top compensation was about $30,000 a year, a company car, and expenses.

Senator PRYOR. Mr. Stanley, is that your feeling as to what the average would be?

Mr. STANLEY. In the area of compensation, I was not involved in any of the four companies to do with that end of the business. Generally, though, it sounds like a fair statement, yes.

Senator PRYOR. What, generally, is the profit made by the hospital on a pacemaker sold to a—reimbursed by medicare, or however the relationship—I am sure there are different relationships between the doctor and the hospital and other parties—but what, generally, does the hospital get out of the sale or the implantation of a pacemaker?

Mr. HOFFERMAN. Well, in most cases, if a pacemaker costs a hospital $2,500, they would probably charge between $4,000 and $5,000 for it.

Senator PRYOR. Do they have to stock the pacemakers?

Mr. HOFFERMAN. It depends on the hospital. In some hospitals, the pacemakers were purchased in advance. In most instances, the pacemakers were stocked in the hospital on a consignment basis.

Senator PRYOR. So they were not out any actual money, but they just stored them there, and then they were used as a passthrough, and they made in the neighborhood of $2,500 per pacemaker?

Mr. HOFFERMAN. If they doubled it, yes, sir.

Senator, can I ask a question of clarification? When we discussed salary, you were referring to a direct salesperson, not an independent representative; is that correct?

Senator PRYOR. I did not know, really, that there was a distinction——

Mr. HOFFERMAN. Yes, sir, there is a big distinction.

Senator PRYOR. What about the sales—the other classification that you mentioned?

Mr. HOFFERMAN. Well, I can tell you that at the company where I worked, it was not unusual for me to write an individual commission check of $30,000 a month.

Senator PRYOR. A month?

Mr. HOFFERMAN. A month, for our top salesman.

Senator PRYOR. I am glad you made the distinction.

Mr. HOFFERMAN. And I guess we considered—well, we considered a salesman that did not earn over $100,000 a year as a failure at Telectronics. And I would like, again, to point two things out. One, we were a very small company in comparison to the "big boys" in the industry, at least in the U.S. marketing place. Second, my salary as sales manager was nowhere near that kind of money.

Senator PRYOR. As a general rule, what does a doctor make on a pacemaker?

Mr. HOFFERMAN. I have heard doctors quote in discussions anywhere from $500 to $2,000. I believe in most cases, they generally take what medicare or other third-party insurance pays in their particular area.

Senator PRYOR. Did you ever consider that some of the incentives for physicians to use your product—did you ever consider that this might be a kickback? Did that ever cross your mind?

Mr. HOFFERMAN. Yes, sir.

Senator PRYOR. And what was your reaction after that? What did you do to cleanse your mind?

Mr. HOFFERMAN. Well, I think the general feeling in the sales and the marketing department where I was was that if we felt that

something was in a gray area, and we were concerned about it—and we were, as official policy of the company—we contacted our attorney and asked for his opinion before we went ahead and did anything.

Senator PRYOR. Mr. Chairman, I know my time has expired.

Senator HEINZ. Senator Pryor, thank you.

Senator Durenberger.

Senator DURENBERGER. Let me start by asking each of you when it was you worked in the pacemaker industry?

Mr. HOFFERMAN. I was with Telectronics from January 1, 1979, to June 2, 1980.

Senator DURENBERGER. Mr. Stanley?

Mr. STANLEY. Intermedics from August of 1975 through December of 1977; Medcor, from January of 1978 through September 1978; and then, Telectronics from September of 1978 through October 1979.

Senator DURENBERGER. Thank you very much.

Let me now ask each of you if you would help us understand a little bit more about the cost to a company—if you will—to compete in this industry with quality products.

Mr. Stanley, you indicated in response to a question that, in your experience, there is a 4-to-1 difference between list price and cost. I assume by "cost," you are talking in general terms of the direct cost of manufacturing; is that correct?

Mr. STANLEY. The only occasion that I had to get involved with understanding the percentage or the markup was at Intermedics, during the early days when they first formed the company, and it was generally understood that they take the direct manufacturing costs and overhead, and it was at the times four multiple to come up with the selling price.

Senator DURENBERGER. Well, because it is a little difficult for us to understand what overhead is, maybe each of you could describe what makes up overhead in this industry.

I assume that you do have a direct cost of manufacture. You also have some costs associated with selling and marketing. In addition, I would assume that they have expenses for research and development. Finally, I assume there are quality control costs, costs of getting approval from the FDA, regulatory costs, and general administrative costs.

Now, having just run through that in a general sense, can each of you give us some kind of a breakdown which might indicate real profit to a company?

Mr. HOFFERMAN. It is a little difficult, because I really was never privy to the bookkeeping principles as they related to the pacemaker. Generally, the information that I had was that it cost in manufacturing costs let us say $500 to manufacture a specific pacemaker. That $500 covered the parts and the manufacturing. We might buy that pacemaker from our manufacturing department for $1,500. That $1,500 should cover their marketing costs, which include such things as research and development, overhead, and so on, including insurance, from what I understood. We then took a look at our overhead, which included rent, marketing, tacked on a certain amount of money there, and our profit, and then we had to

add enough to it to give the salesman enough commission to allow him to go out there and be competitive in the marketplace.

Senator DURENBERGER. Mr. Stanley.

Mr. STANLEY. That information, if I am not mistaken—of course, it is available through publicly held companies in their quarterly or annual financial reports—I would almost have to work backward from the standpoint of sales being the largest percent of overhead as a single entity in the total manufacturing, distribution, research and development, and so forth, cycle, representing somewhere around 23 percent, I believe.

The second largest area or the second and third would be in the G and A and manufacturing. I am sorry I cannot break out the cost of the quality control, which is significant—the remanufacturing, the rejects, and R&D. I do not have any percentages at hand on that.

Senator DURENBERGER. Given what we've heard, I wonder if each of you would give us some advice before you finish about how we, the caretakers of medicare, might change the way in which we do it.

For example, the issue of warranty was brought up earlier in the questioning with the implication that the warranty is sort of free to the companies involved. Reading from the medicare and medicaid guide, page 1,415, I find that those of us on this side of the table have pretty well insured anybody from any risk in this field. The guide says, "There is no provision in the medicare law for subrogation or any other form of reimbursement to medicare by reliable third parties. Therefore, services are covered by medicare even though the beneficiary's need for them resulted from the fault or negligence of another party who is legally liable for the patient's medical expenses, or who has in fact reimbursed the beneficiary for the expenses for such services. The existence of the other party's liability does not affect the beneficiary's obligation to pay for the service he receives. For example, hospital or other provider services needed because of an automobile accident are covered by medicare even though a liability insurer, including a no-fault insurer, is legally obligated to pay for them. Under the Medicare and Medicaid Amendments of 1980, payment is excluded for any items and services to the extent that payment has been made or can reasonably be expected to be made under an automobile or liability insurance policy or plan."

Then it goes on to an interesting example, "Where a defective medical device such as a cardiac pacemaker is replaced under a warranty, hospital or other provider services rendered by parties other than the warrantor are covered despite the warrantor's liability."

Now, clearly, we probably carry as much fault, whoever propounded this legislation and this regulation, as anyone else. Perhaps you could give us some advice not only on this issue, but on the general issue of the role that medicare plays in fostering some of the abuses that exist in the industry.

Mr. HOFFERMAN. When I was with Telectronics, we proposed a program to the Veterans' Administration that we felt would save the Veterans' Administration millions of dollars a year, and I believe that that same type of program could hold true for your gen-

eral medicare patient. I do not know if the program was ever accepted by the VA, but I was at at least two meetings where it was discussed with the hierarchy of the VA here in Washington, and that was that pacemakers be put into specific categories, that all companies manufacturing pacemakers submit the specifics or specs on their pacemaker—price, warranties, this type of thing—to a review committee. It would then be the review committee's responsibility to determine which companies' pacemakers were acceptable in each category, and at what price. Again, you are talking about the cost of the actual pacemaker, warranty of the pacemaker, and of course, the bells and whistles would indicate what particular category they would be put in.

The concern of the VA at the time was how do you get a doctor to use a specific pacemaker in a specific category; doctors generally feel that they are the best person to make that decision, and that is probably correct. I think that if a program like this was initiated, it would make it much more competitive in terms of selling price, which would reduce the price of the pacemaker. It would give the Government control over how the warranties affect the sale of the pacemaker or the reimplantation of the pacemaker. It would certainly give more controls and save money.

Probably the only way you are going to control the physician in terms of what he uses is through some type of committee in each hospital, which has been discussed and was, I believe, discussed on "20/20" last night. Physicians generally only listen to their peers, and again that is correct, because only their peers have the same amount of medical knowledge that they have. We as laypeople certainly are not in a position to tell a physician what he should or should not prescribe.

Senator DURENBERGER. Mr. Stanley.

Mr. STANLEY. To follow up on what Howard was talking about as far as a committee, I believe there are some hospital groups in Canada that require pacemaker approval as far as brand name and model number, by committee, and if you are not on the approved list, then you cannot even, even at a doctor's request, get your pacemaker into that hospital for implantation. They have a much different set of controls on device usage, much tighter than it is here in the United States. I really do not have any suggestions as far as cost containment. I would like to make a comment generally, that a certain portion of the profit level in pacemaking I consider very, very necessary for the research and development. I think we have seen in the last 4 years great strides forward in the type of pacemakers that are available and what you can do with it, either by telephone to monitor or in a nonsurgical procedure, to adjust the pacemaker externally to the patient's changing conditions. I think without—not necessarily the profit level that exists, but it must be a healthy profit level for the companies to pour the kinds of money into research and development to bring these pacemakers out that are improving the quality of life.

Senator DURENBERGER. Thank you.

Senator HEINZ. Senator Durenberger, thank you.

Senator Burdick.

Senator BURDICK. Yes; I have a question. I would like to travel the economic trail of it just for a minute. I understand that the

actual cost of a pacemaker, I think Mr. Hofferman testified, was $500, and I believe that when the pacemaker reached patient "X," it was $2,500 on the lower level; is that correct?

Mr. HOFFERMAN. Generally, when I was involved in the industry, our pacemaker, the one which we marketed more than the others, sold to a hospital for around $2,500. The hospital generally charged third-party insurance anywhere from $5,000 downward. Some of them did have a tack-on fee of, let us say, 10, 15, or 25 percent, but there certainly, from what we understood, were many hospitals that used what is referred to in most industries as keystone. Keystone is, if it costs you a buck, you sell it for two.

Senator BURDICK. Well, we have the cost of the pacemaker at $2,500, the hospital, $5,000. What is the doctor's ordinary charge?

Mr. HOFFERMAN. Again, it is my understanding that it generally ran from $500 to $2,000, depending upon the physician, the hospital, and third-party insurance schedule.

Senator BURDICK. Well, let us take $1,500, then, as kind of an average. I have got $9,000.

Mr. HOFFERMAN. You did not include the hospital stay, the cath lab fees, X-rays.

Senator BURDICK. How much are they?

Mr. HOFFERMAN. You need a second mortgage.

Senator BURDICK. Well, give me a dollar figure.

Mr. HOFFERMAN. You are probably talking—the average hospital stay—and I am not exactly sure—but it probably is 2 to 3 days when you are talking about a pacemaker, and it probably runs about $3,000 to $4,000. Your room is generally about $200, $250 a day, and you have got a charge for your cath lab and everything else. I would think that on the average, by the time the patient gets out of the hospital, it has probably cost anywhere from $8,000 to $15,000.

Senator BURDICK. For one stay, for one operation?

Mr. HOFFERMAN. Yes, Senator.

Senator BURDICK. Well, let us take $10,000, then, as an average. I have got $19,000. Is there any way that can be reduced?

Mr. HOFFERMAN. Well, I think $19,000 would be high, Senator. Maybe I did not make it clear. I would think that we are probably talking between $8,000 to $15,000, depending upon all the circumstances involved.

Senator BURDICK. $8,000 to $15,000?

Mr. HOFFERMAN. Yes, sir.

Senator BURDICK. Is there any way that can be reduced?

Mr. HOFFERMAN. Unfortunately, the cost of the pacemaker is a small percentage of that total cost. It certainly is a percentage of that cost. But I was astonished recently, when I had indigestion, and my wife thought it was something else, just a month ago, and I had to be rushed to the hospital. I was in the hospital for 3 hours, and went home via cab, and got a bill the next week for $600.

Senator HEINZ. It sounds like you were lucky you did not get a pacemaker implanted, as well.

Mr. HOFFERMAN. I know better than that, Senator. [Laughter.]

Senator BURDICK. Of course, to a layman, that seems to be a very exorbitant figure, and if we are going to serve the public, I think there must be some way found to reduce those costs.

Senator HEINZ. I would say to my friend from North Dakota that we are going to have, hopefully, a panel of doctors in the next few minutes, who do have a lot of expertise and who, I expect, will make some good suggestions to us.

Are there any further questions, Senator Burdick?

Senator BURDICK. No; thank you very much.

Senator HEINZ. Senator Pressler.

Senator PRESSLER. Well, we always try to let the free enterprise system work as much as possible, and I guess we have an aversion to Government involvement and want to let things be done through the unfettered free enterprise system. But what does this say about the free enterprise system working in the area of medicine?

Mr. HOFFERMAN. Well, I have always felt, particularly in the 21 years that I was in the medical industry, that a physician should never compromise himself, that it was the physician's responsibility to always use the product which he honestly felt was the best product for that patient's care. I think that what astonished me was that there were even physicians that would take any type of, quote-unquote, kickback. Unfortunately, I think what has happened is that in the atmosphere that prevails in this particular industry, many people have lost sight of what is reasonable and what is not reasonable. Everybody is human, and when you dangle the golden carrot before their nose, and they turn around to their left and their right, and they see, quote, everybody else doing it, which is certainly not the truth, it makes it very difficult for them to say no.

Senator PRESSLER. I might add a bit to that question. What about public service feelings? I have heard in the area of salesmen of feed, and so forth, customers getting trips here and there—of course, we do not consider that, I suppose, so serious because here, in this case, we are dealing with medicine and pacemakers, and life and death. Do people who sell these things have a feeling of public service about what they are doing. Do they feel they are doing good, performing a public service? Do you find that part of the reward for people who are selling pacemakers is that they feel they are engaged in something that is very important in terms of serving their fellow men?

Mr. HOFFERMAN. Senator, most of our salesmen carry beepers to make themselves available when necessary, and I know of many instances where there were problems where the salesman had to get up at 1 or 2 o'clock in the morning, or what-have-you, and go to the hospital to assist a physician, particularly when they were implanting a new style pacemaker. I know for myself, in selling other medical equipment, there were many times when I would just lie down on a bed in the ICU and hope that everybody realized that I was just there, working with the people there.

I got a great deal of satisfaction out of knowing that I was doing some good, also knowing that I was earning a pretty good living at the same time, and I am sure that there are many pacemaker salesmen who feel the same way. Again, just like any industry, there are people who are out there for just one thing, and they do not care how they go about getting it, and that is the buck. It is human nature. So you have got both types.

Senator HEINZ. Senator, can I interrupt, or have you finished?

Senator PRESSLER. I have finished, unless Mr. Stanley has a response.

Mr. STANLEY. I was going to say that I have been in the medical industry my entire working career, and I found generally, throughout the industry, there is a feeling of dedication, particularly with regard to trying to improve the level of patient care. I was with a medical distribution company that my grandfather started, and one of our primary concerns in the selection of products to bring into our stock to distribute and sell was, was it as good as we were stocking or better—never, is it less expensive and the quality, therefore less—but are we going to serve the patient properly. And I think there is a general feeling throughout the industry generally.

I would echo what Howard said, that there are those who do not feel that way and feel the dollar is the Almighty, and that is what they go after.

Senator PRESSLER. Thank you.

Senator HEINZ. Senator Pressler, thank you.

One question. This was a question that Senator Pryor particularly wanted to ask, and I ask it of either of you. Were salespeople involved in, or did they instruct physicians in how to bill medicare, how to get the most out of medicare, in your experience, Mr. Hofferman? And that includes most specifically monitoring.

Mr. HOFFERMAN. I never directly saw any of this take place. However, I did see a film clip, I believe last night, again on television on a news program, where the salesperson was instructing the doctor how they could earn a quarter of a million dollars or whatever it was, by——

Senator HEINZ [interrupting]. By setting up a monitoring clinic?

Mr. HOFFERMAN [continuing]. Setting up a monitoring unit. At the company that I worked for, Senator, we had a monitoring system that we monitored out of Denver, Colo., on an 800 line. It was free to the physician. We pointed out to them that it was free. We charged neither the physician nor the patient nor third-party insurance.

Senator HEINZ. Did the physician, do you know, charge medicare, though, for the monitoring?

Mr. HOFFERMAN. Our comment to the physician was a very simple one: We will supply you with a record of the tracing that we have taken of your patient. If, at the time we take the tracing, we see something wrong, we will immediately call you and not inform the patient, have you inform the patient, that something is wrong and for them to come into your office. If the tracing was routine, we simply mailed that tracing in to the physician.

We then stated to them, "If you want to evaluate that tracing and discuss it with your patient and bill third-party insurance, that is up to you. We do not charge for the service."

Senator HEINZ. So you did not bother to set up clinics, you might say. You just did it for them, and if the physician wanted to charge $25 for routine monitoring, which I guess is what medicare will reimburse, he could——

Mr. HOFFERMAN [interrupting]. Yes, sir.

Senator HEINZ [continuing]. And I assume some did.

Mr. HOFFERMAN. I would assume so, but we did not charge anybody for it, and I never recall in my instances at the company that I was with where somebody said, "Hey, this is a way to make a lot of money." It may have been done, but I never heard it done.

Senator HEINZ. Mr. Stanley, how about in your experience?

Mr. STANLEY. At all three companies where I was employed, as marketing director, we had similar transtelephonic monitoring systems as Howard described. We also offered the doctor, if he wanted to have closer monitoring of his patients, to set up monitoring clinics of his own. We never got involved as far as a philosophy of the company in the instruction of how they can make money on it. It was a service that we offered, either doing it free of charge, by telephone at our home office, or setting their clinics up and training their personnel in how to do it.

Senator HEINZ. You say it was not the philosophy of the company to tell doctors how to make money off of monitoring, but how about the practice of individual salespeople? Do you know of individual salespeople who did, in fact, point out to the doctor that they had no cost in this monitoring, but every time they received a statement from your company that a monitoring had taken place that they could in fact bill medicare for $25?

Mr. STANLEY. I think it would be a fair statement to say generally that the salesmen, especially those on commission, were well informed, or shared information, if you will, about what marketing methods they used, sales methods, in their different accounts.

Senator HEINZ. But do you have any knowledge of a salesman ever telling a doctor, "Look, you can make some money here"?

Mr. STANLEY. No, sir.

Senator HEINZ. I thank our witnesses. I would just like to make one observation. Back in 1977, this committee estimated there was about $3 billion being stolen or wasted in medicare and medicaid programs each year. In March of this year, this committee, in investigating some of the practices of excesses of hospitals operating in the medicare program, we estimated that about $4 billion of the $58 billion Senator Domenici described as being lost through fraud, waste, and abuse. Today, I think we have to add to that total a minimum of close to $1 billion. So instead of $3 or $4 billion, the total is now $5 billion, just by virtue of this one program, less than 1.7 percent of the entire medicaid program. I think that is a shocking figure. It is shocking not only to the taxpayer, but when you realize the pressure that all Federal programs are under to reduce, to economize, to cut back, what it means is that salesmen are making $1 million, while medicare beneficiaries are under pressure to pay more or go without. It is not a situation that this committee countenances. It is not something that the members of this committee believe can be left alone. That is the purpose of this investigation.

Senator Durenberger has spoken eloquently about the need to reform our health care system and particularly the way its perverse incentives today operate. I believe that the time for reform is long overdue.

I thank all of you for being here today.

Senator Pressler, I have to step out for a minute. Would you be willing to Chair the hearing during my absence?

Senator PRESSLER. Yes.

Senator HEINZ. Gentlemen, thank you very much.

Senator PRESSLER [presiding]. We will call our next panel of witnesses forward at this time, who are Dr. Seymour Furman, of the Montefiore Hospital and Medical Center, New York, N.Y.; Dr. Mark Blum, Colorado Springs, Colo.; Dr. Peter R. Kowey, director of the coronary care unit, Medical College of Pennsylvania, Philadelphia, Pa.; Dr. Brendan Phibbs, chief of medicine and director of cardiology, Kino Hospital, Tucson, Ariz.

Three of the four doctors have prepared statements. First of all, thank you very much for being here. We appreciate your coming before the Aging Committee.

I would like to first call upon Dr. Furman, who has a prepared statement.

PANEL NO. 3. PHYSICIANS

STATEMENTS OF DR. SEYMOUR FURMAN, MONTEFIORE HOSPITAL AND MEDICAL CENTER, NEW YORK, N.Y.; DR. MARK F. BLUM, COLORADO SPRINGS, COLO.; DR. PETER KOWEY, DIRECTOR, CORONARY CARE UNIT, MEDICAL COLLEGE OF PENNSYLVANIA, PHILADELPHIA, PA.; AND DR. BRENDAN PHIBBS, CHIEF OF MEDICINE AND DIRECTOR OF CARDIOLOGY, KINO HOSPITAL, TUCSON, ARIZ.

Dr. FURMAN. Senator Pressler, thank you for inviting me and giving me the opportunity to be here today. I do have a prepared statement in which I will describe the pacemaker field and make some comments about it.

The first implantable pacemaker of 1958 lasted 8 hours. The second, a similar rechargeable device, lasted another 8 days before it failed. Today, immensely more complex devices are predicted and probably will last 8 to 10 years.

The old devices were simple, attempted to stimulate the heart with a regular, unvarying stimulus rate of approximately 60 to 70 beats a minute, to treat complete heartblock, the simplest condition which can be treated by a pacemaker. Complete heartblock, the classic arrhythmia to be so treated, is a condition in which the upper chambers, the atria, and the lower heart chambers, the ventricles, beat independently of each other. The ventricles, the main pumping chambers, may then pump slowly and erratically. They are likely to stop briefly or for several seconds, causing the flow of blood to cease and producing an episode of dizziness, fainting, convulsions or death, all based on the duration of the period without a heartbeat.

Senator PRESSLER. Excuse me. I want to have order in the room. The people in the rear, conversing, and on the side, please carry on your conversations outside the room, because we do want to have Dr. Furman's statement. And Dr. Furman, if you could be a little closer to that microphone.

Dr. FURMAN. Usually, such periods without a heartbeat of several seconds' duration cause moderate symptoms; longer periods of 10 or 15 seconds cause more severe symptoms; obviously, longer periods than that, cause death. Complete heartblock can be treated by a stimulation device set at an unvarying rate of about 70 beats per

minute for an adult and faster for a child. That device does not sense the heart's spontaneous activity and, of course, does not respond by modifying its own actions.

As the upper pumping chambers, that is, the atria, are far more sensitive to body needs than the ventricles, it is they in the normal which set the heart rate and vary it as necessary with activity or motion. In the case of complete heartblock and with good heart muscle function, a great deal of adjustment to body requirements can be accomplished, and a patient can be restored to a substantially normal life. But as long ago as 1958, the first efforts were made to recognize the atria as necessary in restoration of the normal sequence of heart beat, that is, the atria beating first at whatever rate was necessary, then a pause to allow expulsion of blood from the atria to the ventricles, followed by a beat of the ventricles to drive the blood through the remainder of the body. This proved to be a far more complex problem than stimulating the ventricles at a fixed, regular rate.

While several commercially available units with that capability became available, they never reached widespread success or utilization because of the complexity involved. Since the beginning of the 1960's, there has been a medical/technical effort to restore the normal sequence of cardiac contraction; this effort is only now beginning to be successful because of the availability of modern circuits capable of responding rapidly to changing requirements based on the sometimes independent beating of the two sets of cardiac chambers.

The classic arrhythmia, complete heart block, now accounts for only about one-fifth of all pacemaker implants. Far more complex arrhythmias, especially those which involve the ratesetting chambers of the heart, the atria, are now corrected by pacing more frequently than for complete heartblock. Partial, incomplete, or intermittent heartblock is commonly corrected by pacing, and one of the disputes of the field involves the determination of which lesser levels of block are precursors of complete heartblock and its ominous consequences.

Almost as commonly treated by pacing is sinus node disease, disease of the atria. Because symptoms may be troubling and even disabling, but uncommonly cause death, the indications for pacing these patients are frequently in more dispute than for complete heartblock. As there is no effective drug therapy for either heartblock or sinus node disease, the disagreement concerning the latter frequently surround the question of just what level of disability is acceptable without pacing.

The simplicity of the descriptions given above, I must emphasize, belies the complexity of the effort now underway, which attempts to restore the normal pattern of the beating of the heart at a normal rate and with normal responsiveness.

At their most effective, pacemakers can restore substantially good cardiac health to some who may die suddenly or otherwise be chronically disabled. At least they will restore comfort and moderate functional ability to one who would be slightly or perhaps substantially disabled.

The newest and certainly the most complex pacemaker therapy is that for very rapid heart rhythms, that is, supraventricular ta-

chycardias, those of the atrium, and ventricular tachycardias, those of the lower chamber, which are far more dangerous. These diseased heart rhythms have been investigated and defined over the past decade with the help of techniques of electrical stimulation of the heart. Many methods of ending them are under intensive investigation, including medication, surgery, and pacemaker therapy. As the ability to analyze the stimulation pathways within the heart grows, it is likely that pacemaker value and complexity will grow.

To this date, there have been few enforced criteria for training in the implant of a cardiac pacemaker, or in the management of the device after implantation. While the Board of Thoracic Surgery has established criteria for pacemaker implant, these are minimal and, it is my impression, widely disregarded.

The 1974 report of the Inter-Society Commission for Heart Disease Resources, which I will refer to as the ICHD from here on, included a statement concerning training. It is my experience that that portion of the report, too, has been widely disregarded. Many university affiliated institutions allow a resident in thoracic and cardiovascular surgery and in cardiology to complete training without significant exposure to implanted cardiac pacing. Many of these residents will, of course, go on to the implantation of and the management of patients with cardiac pacemakers.

Possibly, this is a result of the growing importance of the nonsurgeon, the cardiologist, in pacemaker implant and the reluctance of either surgeons or cardiologists to intrude upon a "sister" specialty. Whatever the reason, there have been few professional standards set in pacing.

At an individual institution, criteria may be established by a credentials committee, but the implantation and observation of implanted pacemakers by one or more staff members is usually decided by the usual patterns of who it is that delivers a specific service at a hospital, especially if that delivery is not specifically mandated by national professional societies.

There are today about 500,000 people in the United States with implanted pacemakers. The number appears to increase by about 100,000 annually, so that professional criteria are required. In 1979, the North American Society of Pacing and Electrophysiology, NASPE, was formed to begin the effort at providing a coordinated educational and professional experience. Membership has so far been limited to professionals and a few in industry with very adequate credentials. A more formal setting of professional standards is to come. At present, in addition to medical and scientific conferences, NASPE has sponsored "policy" conferences, one on resources for pacemaker implantation, this past March in Chicago and a forthcoming conference the second week in October on the clinical evaluation of new implantable pacemakers.

Professional criteria and standards are necessary, and many will be suggested by the forthcoming ICHD report, which is now in the final stages of preparation and is a revision of the 1974 report.

Senator PRESSLER. Pardon me. I will have to ask you to summarize.

Dr. FURMAN. I'd like to comment on two other points. One is about the pacemaker registry and the other is the position that has been taken about salespeople in the operating room, for which I'd

like to read about one page of text taken directly from the ICHD report:

"The role of cardiac pacemaker company sales representatives or industry clinical specialists requires comment. Many hospitals in which pacemakers are implanted do not have adequate resources of technical expertise or equipment. In 50 percent of hospitals in which pacemakers are implanted, fewer than 40 procedures per year are performed. A consequence of these inadequacies is the involvement of sales representatives as a resource for many of the technical and professional requirements which have been described.

"It appears that in at least half of permanent cardiac pacemaker implantations, such persons are in attendance in the operating room. The ultimate responsibility for implantation and its consequences rests with the implanting physician. Responsibility for providing trained support personnel rests with the hospital. An industrial representative is an incidental resource whose services may be used only under specific and unusual circumstances and who should not be an assistant for implanting pacemakers. In some jurisdictions, incidentally, the presence of nonhospital personnel in the operating room is illegal.

"If unusual circumstances exist, and an industrial representative is needed in the operating room, the hospital should require documentation of his or her training in pacemaker electrophysiology, the use of pacemaker systems analyzers and programers, and the basics of operating room procedures, decorum, and sterility. Under no circumstances should such an individual be allowed to have direct contact with the patient either before, during, or after the procedure. A specific notation should be made in the operating room record of the presence of such an individual and his role, direct or indirect, in the procedure.

"In unique circumstances, such as the use of pacemaker systems that are under clinical investigation"—which I might add parenthetically is mandated and controlled by the Food and Drug Administration—"A properly qualified industry clinical specialist may be necessary and helpful. In this case, the patient should be informed and the fact documented for the record."

My last comment in summary is regarding pacemaker registries. A proposed pacemaker registry would be of great value. It is relatively more possible to develop such a registry for implantable pacemakers than, for example, for drugs, because each unit is discretely identified by individual model and serial number and implanted in a single person. No secondary market exists.

A registry for determination of pacemaker quality had been sponsored by the Food and Drug Administration from 1974 through 1981, first for three and later for five centers. While the registry provided information concerning the function of a large variety of pulse generators, it reflected the usage patterns only of the physicians involved and, correspondingly, did not represent the usage patterns of the Nation.

Although we lost our funding at the end of 1981, all of us who were part of the registry have maintained excellent relations with

the people in the Food and Drug Administration, who still continue to call upon us periodically for advice.

Senator PRESSLER. Thank you.

[The prepared statement of Dr. Furman follows:]

PREPARED STATEMENT OF DR. SEYMOUR FURMAN

The first implantable pacemaker, of 1958, lasted 8 hours; the second, a similar rechargeable device, lasted another 8 days before it failed. (Today, immensely more complex devices are predicted, and probably will last, 8 to 10 years.) These were simple devices which attempted to stimulate the heart with a regular, unvarying stimulus rate of 60 to 70 beats per minute to treat complete heartblock, the simplest condition which can be treated by a pacemaker. Complete heartblock, the classic arrhythmia to be so treated, is a condition in which the upper heart chambers, the atria, and the lower heart chambers, the ventricles, beat independently of each other. The ventricles, the main pumping chambers, then pump slowly and erratically. They are likely to stop briefly or for several seconds causing the flow of blood to cease and producing an episode of dizziness, fainting, convulsions, or death, all based on the duration of the period without a heartbeat. Usually such periods without a heartbeat of several seconds duration cause moderate symptoms; longer periods of up to 10 to 15 seconds cause more severe symptoms. Complete heartblock can be treated by a stimulation device set at an unvarying rate of about 70 beats per minute for the adult. That device does not sense the heart's spontaneous activity and, of course, does not respond by modifying its own actions.

As the upper pumping chambers (the atria) are far more sensitive to body needs than the ventricles, it is they, in the normal, which set the heart rate and vary it, as necessary, with activity or emotion, etc. In the case of complete block and with good heart muscle function, a great deal of adjustment to body requirements can be accomplished and a patient can be restored to a substantially normal life. As long ago as 1958, the first efforts were made to recognize the atria as necessary in restoration of the normal sequence of heart beat, atria beating first (at whatever rate was necessary) then a pause to allow explusion of blood from atria to ventricles, followed by a beat of the ventricles to drive the blood through the remainder of the body. This proved to be a far more complex problem than stimulating the ventricles at a fixed, regular rate. While several commercially available units with that capability became available they never reached widespread success or utilization because of the complexity involved. The medical-technical effort, since the beginning of the 1960's, has been to restore the normal sequence of cardiac contraction, an effort which is only now beginning to be successful because of the availability of modern circuits capable of responding rapidly to changing requirements based on the sometimes independent beating of the two sets of cardiac chambers.

The classic arrhythmia, complete heartblock, now accounts for only about one-fifth of all pacemaker implants. Far more complex arrhythmias, especially those which involve the ratesetting chambers of the heart, the atria, are now corrected by pacing more frequently than for complete heartblock. Partial, incomplete, or intermittent heartblock is commonly corrected by pacing, and one of the disputes of the field involves the determination of which lesser levels of block are precursors of complete heartblock and its ominous consequences. Almost as commonly treated by pacing is sinus node disease, that of the atria. Because symptoms may be troubling but uncommonly cause death, the indications for pacing these patients are frequently in more dispute than those for heartblock. As there is no effective drug therapy for either heartblock or sinus node disease, the disagreement concerning the latter frequently surround the question of what level of disability is "acceptable" without pacing.

The simplicity of the descriptions given above belies the complexity of the effort now underway, which attempts restoration of the normal pattern of beating of the heart at a normal rate and with normal responsiveness.

At their most effective, pacemakers can restore substantially good cardiac health to some who may die suddenly or otherwise be chronically disabled. At least they will restore comfort and moderate functional ability to one who would be slightly or perhaps substantially disabled. The newest and certainly the most complex pacemaker therapy is the of rapid heart rhythms, supraventricular (those basically of the atrium, the upper chamber and ventricular (those basically of the lower chamber—and far more dangerous) tachycardias. These diseased heart rythms have been investigated and defined over the past decade with the help of techniques of electrical stimulation of the heart. Many methods of ending them are under intensive in-

vestigation, including medication, surgical, and pacemaker therapy. As the ability to analyze stimulation pathways within the heart grows, it is likely the pacemaker value will grow.

PROFESSIONAL CRITERIA

To this date there are few enforced criteria for training in the implant of a cardiac pacemaker, or the management of the device after implantation. While the Board of Thoracic Surgery has established criteria for pacemaker implant, these are minimal in nature and, it is my impression, are widely disregarded. The 1974 Inter-Society Commission for Heart Disease Resources (ICHD) report included a statement concerning training. It is my experience that that portion of the report has been widely disregarded. Many university-affiliated institutions allow a resident in thoracic and cardiovascular surgery and in cardiology to complete training without significant exposure to implanted cardiac pacing. Many of these residents will, of course, go on to the implantation of and management of patients with cardiac pacemakers.

Possibly this is the result of the growing importance of the nonsurgeon, the cardiologist, in pacemaker implantation and the reluctance of either surgeons or cardiologists to intrude on a "sister" speciality. Whatever the reason, there have been few professional standards set in pacing. At an individual institution criteria may be established by a credentials committee, but the implantation and observation of implanted pacemakers by one or more staff members is usually decided by the usual patterns of who it is that delivers a specific service at a hospital, if that delivery is not specifically mandated by national professional societies.

There are 500,000 people in the United States with implanted pacemakers. The number increases by about 100,000 annually, so that professional criteria are required. In 1979, the North American Society of Pacing and Electrophysiology (NASPE) was formed to begin the effort at providing a coordinated educational and professional experience. Membership has been limited to professionals and a few in industry with adequate credentials. A more formal setting of professional standards is to come. At present, in addition to medical and scientific conferences, it has sponsored policy conferences on "Resources for Pacemaker Implantation" and a forthcoming conference on "Clinical Evaluation of New Implantable Pacemakers."

Professional criteria and standards are necessary and many will be suggested by the forthcoming ICHD report, now in the final stages of preparation.

INSTITUTIONAL REQUIREMENTS

Aside from the "bricks and mortor" facilities required, personnel should possess skills specifically required for pacemaker implant. Many institutions do not have nonprofessional staff people trained in pacemaker work. Pacemaker sales representatives therefore are involved in many of the implants performed in the United States. They provide the technical support. This is inappropriate. The ICHD report makes the following statement in the 1982 version:

"The role of cardiac pacemaker company sales representative or industry clinical specialists requires comment. Many hospitals in which pacemakers are implanted do not have adequate resources of technical expertise or equipment. In 50 percent of hospitals in which pacemakers are implanted, fewer than 40 procedures per year are performed. A consequence of these inadequacies is the involvement of sales representatives as a resource for many or the technical and professional requirements which have been described. (It appears that in at least half of permanent cardiac pacemaker implantations such persons are in attendance in the operating room.) The ultimate responsibility for implantation and its consequences rests with the implanting physician. Responsibility for providing trained support personnel resides with the hospital. An industrial representative is an incidental resource whose services may be used only under specific and unusual circumstances, and who should not be an assistant for implanting pacemakers. In some jurisdictions, incidentally, the presence of nonhospital personnel in the operating room is illegal.

"If unusual circumstances exist and an industrial representative is needed in the operating room, the hospital should require documentation of his training in pacemaker electrophysiology, the use of pacemaker systems analyzers and programers, and the basics of operating room procedures, decorum, and sterility. Under no circumstances should such an individual be allowed to have direct contact with the patient either before, during, or after the procedure. A specific notation should be made in the operating room record of the presence of such an individual and his role, direct or indirect, in the procedure. In unique circumstances, such as the use of pacemaker systems that are under clinical investigation, a properly qualified indus-

try clinical specialist may be necessary and helpful. In this case the patient should be informed and the fact documented for the record."

COSTS

A pacemaker is an expensive device which must carry a large technical development burden. Because a sales representative is involved in so many implants there is a heavy cost added to the unit for his/her time. No "generic" pacemaker has become available and despite the appearance of some price softening the pacemaker remains expensive. As a pacemaker is never reused, should the patient in whom it is implanted die, after a relatively brief period of pacemaker use, a good device is lost. A possibility, several times considered but not instituted, is that of reuse of a device with substantial longevity remaining. The problems of evaluation of the "reused" device, who is to refurbish and warranty it, and the avoidance of fraud, are significant issues if this approach is to be taken.

Modern pacemakers can fail because of electronic circuit malfunction or battery depletion. If so, a warranty is available from the manufacturer. It is, however, the responsibility of the physician or hospital staff to be certain that the financial credit is requested. With so many pressures on time and cost coming from a budget not under the doctor's control it is likely that many warranties are not pursued. Institutions should be encouraged to avail themselves of available warranties. But as pacemakers become longer lasting and more reliable (and they are) such retrieval of funds will become less and less of a significant factor in costs.

PACEMAKER REGISTRY

A proposed pacemaker registry would be of great value. It is relatively more possible to develop a registry for implantable pacemakers than for drugs because each unit is discretely identified by individual model, serial number, and implanted in a single person. No secondary market exists. A registry for determination of pacemaker quality had been sponsored by the Food and Drug Administration from 1974 through 1981 first for three and later for five centers. While the registry provided information concerning the function of a large variety of pulse generators, it reflected the usage patterns of the physicians involved and correspondingly did not represent the usage patterns of the Nation as a whole. Also, while the information concerning lead systems existed in the registry, funds for analysis of lead function have never been available. The registry lost its funding at the end of 1981, and while it continues at a low level of activity, primarily the intake of data, its survival is at the mercy of resources available at each institution. This registry, intended to advise the FDA, has not been of direct benefit to the patient population.

A more useful registry would be one in which each patient implanted in the United States would be enrolled. The patient benefits would be significant if a technique of a pacemaker "passport," already developed in Europe, were followed. There, each patient is given a passport-like book containing data about patient, diagnosis, pacemaker, settings of the pacemaker, medication, etc. In the United States this would be especially valuable as medical attention is often shared between physicians who do not have ready communication. Finding a patient with a pacemaker that is being recalled would be easier as all patients would be recorded in a central file.

Regulatory agencies would have access to data concerning the quality of all pacemakers. Decisions concerning recall and warranty could be assisted by actual experience with the device. Such experience could be provided to the profession without specific regulatory action to enable appropriate medical decisions involving the devices.

Manufacturers would benefit from knowledge of the utilization patterns and overall quality of the devices they produce. Where a dispute with regulatory agencies arose over a specific device, both sides would have data from a common source to assist in a decision. Such data is not now available.

The profession would benefit by dissemination of knowledge concerning the quality of the devices implanted. Proper protection of sensitive data concerning patient, physician, and even manufacturer, concerning commercial and competitive requirements, should be mandatory. There is long experience with such requirements and such security should readily be accomplished.

Senator PRESSLER. We are going to have to move through the other three statements, and if we could, please watch the time a little bit.

I am going to call on Dr. Blum, to simply state in his own words, the circumstances that led him to believe a pacemaker salesman had offered a kickback, and his subsequent actions. I think his actions were the first that triggered this whole thing, as I understand it.

Dr. BLUM. Well, what happened was that I was putting a pacemaker in in one of the hospitals in Colorado Springs in the summer of 1980, and following the implantation of that particular pacemaker, I was confronted by the representative from the particular company who was there at the time, and he indicated to me that there was a new program out by his pacemaker company which would reimburse the individual for the expenses incurred in the pacemaker implantation. At first, I thought that was a reimbursement to either the hospital or to myself in the usual fashion through some paperwork reimbursement that could offset the costs, or a deduction in the cost of the pacemaker itself. On a little bit more of a query, it turned out that what was being said to me was that a check for $500 could be directly made out to me whenever I replaced a pacemaker with this particular company's pacemaker circuitry and battery. And at that point, under the system that we have in Colorado, in any event, when you have somebody in the hospital and you end up having to put in a medicare—or at least, you must put in some kind of a physician's fee, a bill for hospitalization and implantation of pacemaker or other operative procedure—I realized that that was a direct check, and I was having trouble interpreting any other way the $500 under the table every time I used one of their pacemakers.

At that point, I cannot say what I said, but I suggested that he not show up back in the institution and that I did not care to see his pacemakers there. I went to the hospital administrators of two of the institutions and related what had happened and said, "I do not think I would like to see that gentleman and his pacemakers in this hospital, if I have anything to say about it." In the one hospital, I evidently had enough to say about it, because neither he nor his pacemakers showed up, and that hospital administrator called Denver, to the medicare office, asking how he could be sure that any reimbursements that might have come from that particular pacemaker company had been duly credited and that the hospital had not double billed. I do not know what his answer was, and I did not know much about what else happened until Mr. Griffin from Denver, in the Office of Investigations of the Department of Health, Education, and Welfare, showed up in my office.

I do have, in answer to one of the questions that Senator Burdick asked, one of the bills, and actually, it is the bill of that particular lady, in whom I implanted a pacemaker and then had the followup conversation with the salesman, and it is lacking only two things, the cardiologist's bill and my bill. You are welcome to look at it. Her total hospital bill was $6,008, and the pacemaker bill was $5,267.45.

Senator HEINZ [resuming chair]. Dr. Blum, does that complete your testimony?

Dr. BLUM. I did not have a written statement. I was responding to his question.

Senator HEINZ. I would like to thank Senator Pressler for chairing these hearings, as he has done on several occasions this morning; it is most appreciated.

What we will do is have all of you make your statements, and then we will have questions.

Dr. Kowey.

Dr. KOWEY. Thank you, Senator Heinz.

I will try to be brief. I would like to review with you, and the committee, the evidence to date that artificial cardiac pacemakers are being implanted unnecessarily in a significant number of patients.

The concern over this issue has been fueled in large measure by four major studies which have been carried out over the last 3 years. The first was a study which I conducted in cooperation with Dr. Bernard Lown at the Peter Bent Brigham Hospital and Harvard Medical School. We had the opportunity to evaluate 31 patients who had already undergone a pacemaker implantation before they were referred to us. After a detailed in-hospital evaluation, we recommended that 10 of the implants had been performed unnecessarily, and consequently recommended generator removal.

This study was followed by that of Chokshi and Friedman which was published in the Journal of the American Medical Association. Because of a sharp increase in the number of implants at the Brooklyn Hospital, a peer review committee was established to monitor subsequent implants. Total implants declined from 48 to 22 per year in the 2 years that followed institution of the panel, including a fall from 32 to 5 in the number of implants for an indication called intraventricular block, which is generally not considered to be a solid reason for pacemaking. Furthermore, 3-year survival of patients after implantation improved from 57 to 86 percent during the peer review.

Drs. Lindenberg and Levine from Boston University reported at the North American Society of Cardiac Pacing and Electrophysiology that 24 percent of the 59 pacemakers implanted at a community hospital in Boston in 1980 could not be justified. These results contrasted sharply with the survey at a university hospital during the same year, in which no unnecessary implants could be found.

Finally, the Health Research Group, for whom I consult, recently completed a survey, the results of which were sent to Secretary Schweiker. We reviewed the discharge diagnoses of 2,222 patients who underwent permanent pacemaker implantation in 1979 and 1980 in the State of Maryland. We used very liberal criteria to establish the necessity of an implant. For example, any patient who experienced loss of consciousness was deemed to have been a fair candidate for pacemaking, even though a cardiac rhythm disturbance may not have been decisively demonstrated.

We also identified a number of other criteria which could be proper criteria under appropriate circumstances, but which by themselves could not be used as a justification.

Finally, we designated a number of diagnoses which could not be used as a rationale for pacemaker implantation. A list of these diagnoses in each category follows.

Pacemakers deemed necessary if implanted for one of the following reasons:

426.0—AV block complete (third degree AV block).
426.12—Mobitz II AV block (incomplete AV block: Mobitz II; second degree, Mobitz II).
426.54—Trifascicular block.
426.6—Other heartblock (intraventricular block: not otherwise specified, diffuse, myofibrillar; sinoatrial block: sinoauricular block).
426.9—Conduction disorder, unspecified (heartblock not otherwise specified; Stokes-Adams).
427.81—Sinoatrial node dysfunction (sinus bradycardia: persistent, severe: sick sinus, tachy-brady.
780.2—Syncope and collapse (blackout, fainting, vasovagal attack).

Pacemakers deemed "questionable" if implanted for one of following indications:

426.3—Other left bundle branch block (LBBB: not otherwise specified, anterior fascicular with posterior fascicular, complete, main stem).
426.50—Bundle branch block, unspecified.
426.51—Right bundle branch block and left posterior fascicular block.
426.52—Right bundle branch block and left anterior fascicular block.
426.53—Other bilateral bundle branch block (bifascicular block not otherwise specified, bilateral bundle branch block not otherwise specifed, right bundle branch with left bundle branch block (incomplete), (main stem)).
426.89—Other conduction disorders (dissociation: AV, interference, isorhythmic; nonparoxysmal AV node tachycardia).
427.1—Paroxysmal ventricular tachycardia (ventricular tachycardia (ventricular tachycardia (paroxysmal)).
427.9—Cardiac dysrhythmia, unspecified (arrhythmia (cardiac) not otherwise specified).
746.82—Congenital heartblock (complete or incomplete AV block).

Examples of diagnoses not considered sufficient to justify a permanent pacemaker:

426.4—Right bundle branch block.
426.13—Other second degree AV block (incomplete AV block: Mobitz type I).
428.0—Congestive heart failure.

We found that only 64 percent of the implants performed in Maryland in those 2 years could be justified, and that 22 percent were unnecessary. An additional 13 percent were questionable.

What is the significance of these findings? In my mind, there are really two major issues. The first, and probably the most important, is that unnecessary pacemaker implantation causes human suffering, not only from unneeded surgical procedures, but also by the general concern that the patient may have over the health of his or her heart. Second, a profligate policy of pacemaker implantation obviously exacts a heavy financial cost.

There are well over 100,000 pacemaker implants in this country per year, as we have heard, which is parenthetically two to three times the number inserted per capita in other Western countries, such as the United Kingdom and Canada. Each implant costs between $7,000 and $8,000. The cost of routine followup care for a patient adds an additional $4,000 to $5,000 to the lifetime expenditure. If 25 percent of these implants are unnecessary, as these studies indicate, the cost of unneeded pacemaker insertion will be over a quarter of a billion dollars per year. Assuming that medicare will pay for 75 percent of these unnecessary pacemakers, as it did in Maryland, the Federal Government is spending $210 million every year on an unnecessary and potentially dangerous procedure.

There are those who question whether our estimation of the problem is accurate, and I will admit that no study to date has been completely unflawed, either in its design methods or its sampling procedures. But to simply ignore the remarkable consistency of the results of studies to date, performed by multiple and, I know, honest investigators, is to display a remarkable lack of insight. There is no question that we are dealing with a problem of large magnitude, the dimensions of which, based on more recent evidence, may be even greater than what we have outlined.

To what may we attribute this phenomenon of unnecessary pacemaker implantation? First, you should realize that these are, as Dr. Furman has outlined, very complex medical issues, and that there does not yet exist a uniform set of criteria for pacemaker implantation available nationally. Furthermore, many physicians who implant pacemakers, or who recommend implantation, are inadequately trained to assess the subtleties of complex arrhythmia problems. The tremendous financial incentives to implant these devices invite the avarice and greed, to which I am sorry to say, even we physicians are liable. Finally, technology is by its nature seductive, and the opportunity to employ a complex medical device to solve a perplexing, and at times exasperating, medical problem can be alluring.

There are no easy solutions. However, we do recommend a three-pronged attack. First, there should be a set of uniform standards, decided by leading pacemaker specialists, concerning the proper indications for pacemaker implantation. This should be coupled with an aggressive program of physician education, conducted at a local and national level. Second, we would recommend a process by which all implantations would be reviewed by a peer group, either at the hospital or local medical association level. In lieu of this review process, a second opinion would be mandated. Finally, careful surveillance of the pacemaker industry appears necessary to preclude business interference with the conduct of proper patient care.

As a physician, I must say that I am personally saddened that this problem has developed, and further saddened that we have found it necessary to go outside of our profession to solve it. However, to continue to ignore the problem is to abandon our responsibility to our patients, as well as to our profession.

Senator HEINZ. Dr. Kowey, thank you.

Dr. Phibbs.

Dr. PHIBBS. Thank you, Senator.

I will speak to the specific issue of overutilization, by which I mean improper implantation of the pacemaker.

Senator HEINZ. Dr. Phibbs, I apologize. We did issue a friendly subpena to you. Therefore, I am compelled to swear you in.

Dr. PHIBBS. Yes.

Senator HEINZ. Do you swear that what you are about to say is the truth, the whole truth, and nothing but the truth?

Dr. PHIBBS. Yes.

Senator HEINZ. Thank you. Please proceed.

Dr. PHIBBS. I have been involved in pacemaker technology since the days when I was the only cardiologist in a large part of the Northern Rockies, and implanted the first pacemakers in the area, and spent a lot of time touring Wyoming, teaching people in remote hospitals how to do this on an emergency basis.

When I moved to the faculty of the University of Arizona, I made all decisions on pacemaker implantations for the University Hospital, until I moved over to be chief of medicine at my present hospital. So I have been involved for a long time, and I say this to weigh the effects of what I am going to say.

None of us were aware of this problem, or some of us weren't, until in Tucson, the cases you have heard of previously were brought to our attention. Two physicians appeared to have been implanting pacemakers inappropriately, and another physician and I, a cardiologist at another hospital and I, were appointed by a court to review 24 sequential pacemaker insertions. We found that of the 24, 4 were clearly necessary, and 3 might have been indicated in the gray area if you strained your imagination a lot, and the remainder could not be justified by any stretch of the imagination.

This was startling. We thought it was local, isolated, but when the lawsuits began flying back and forth, and eight cases were filed for malpractice, and people were brought in from around the country to testify, we found on reviewing depositions from people from other parts of the country that there was evidence of the same kind of inappropriate pacemaker insertion or, bluntly, malpractice.

We were concerned enough about this so that I brought this to the attention of the electrocardiographic standards committee of the American College of Cardiology, of which I am a member. There are eight of us for the United States who try to help set standards in electrocardiography. At our Atlanta meeting this spring, we agreed that this was a serious problem in everyone's experience, and I was delegated as liaison to the pacemaker committee, chaired by Dr. Parsonnette, a very distinguished authority in the field who I think is in the room, to set up communication to reach agreement on reasonable standards, indications for pacemaker insertion.

So what I am saying next is not the official findings of the committee, but they will be my personal observations as a result of conversations with cardiologists from the west coast, the east coast as far down as Florida, and even in England.

The pattern is spotty. At a university hospital or a major hospital, you might find close to 100-percent suitability of performance. In other areas, the rate of malutilization will be way over the 50-percent figure. It has been truly—I will use a strong word—shocking to me.

Imaginary syndromes have been invented to justify pacemaker insertion—things that do not even exist. One west coast cardiologist uses the term, "chronotropic incompetence." Did either of you ever hear that one?

Dr. KOWEY. No.

Dr. FURMAN. No.

Dr. PHIBBS. And Dr. Furman, by the way, is the man who invented pacemaking. He is being a little modest in his statement. And if he has not heard it, nobody has. Anyway, this means that your heart, although all the systems are apparently "go" in current parlance, is beating too slowly for the needs of your body. This is a nonexistent disease, and yet it is used to justify pacemaker insertion.

The skipped beats—everyone here who has been tired and drunk too much coffee and smoked too many cigarettes has had their heart skip a beat, right? When these arise from the bottom chambers or ventricles, they are a little more troublesome. You only treat them really if the patient has had a heart attack or in the period immediately after. Very rarely do they need treatment. And yet people go to a doctor with these skipped beats, and they are told, "Oh, we must treat the skipped beats. Now, the drugs we may give you may slow your heartbeat somewhat, and therefore, we will put in a pacemaker to enable us to treat these skipped beats that did not need treatment in the first place."

In other words—this is in more detail in my prepared statement.

Senator HEINZ. By the way, without objection, your entire statement will be made part of the record.

Dr. PHIBBS. Thank you.

So what I want to say in summary, finally, are two things. The abuse does exist, and you can get numbers that vary from 10 percent to 80 percent, depending on who you are talking to and what their experience has been. I think they are probably all valid in certain localized settings.

Second, we stopped this in southern Arizona, and we did it through the PSRO, your agent. We did it because we convened a committee of which I had the privilege to be chairman, to set up standards for invasive cardiology, generally. Partly as a result of the publicity from the malpractice suits that were filed, and partly through carefully promulgating these standards to every physician in our region, with plenty of time for review, I think we have brought the practice of inappropriate pacemaker insertion to a halt in our area. I think that is not overstating it. It can be done anywhere.

Thank you.

[The prepared statement of Dr. Phibbs follows:]

PREPARED STATEMENT OF DR. BRENDAN PHIBBS

In Tucson, Ariz., we became aware of the possibility of pacemaker abuse because of legal actions filed against practitioners in one hospital. Under court order, the chief of cardiology at another local hospital and I reviewed 24 cases of pacemaker implantation and found that, making the most liberal assessment possible, and making every assumption in favor of the physician, we could clearly justify 4, and possibly 7 cases, out of the 24. Subsequent review of sworn testimony and depositions taken in various parts of the United States, as well as evidence gathered informally by our colleagues in a number of major cardiac centers, has convinced us that

at least in some centers and in some parts of this country, abuse of pacemaker technology is a serious problem.

The abuse takes several forms:

(1) Patients manifesting harmless variants of heart rhythm or intracardiac conduction, which are in no sense a threat to life or health, are subjected to pacemaker insertion.

(2) Abnormalities of the electrocardiogram or of electrophysiologic measurements are detected in patients who are taking cardiac drugs that clearly are capable of producing these abnormalities. The patient is informed that a pacemaker is needed when, in fact, all that is necessary is a discontinuance of the drug or a change to a different type.

(3) Patients presenting with minimal symptoms, clearly not incapacitating or hazardous, are subjected to involved, expensive diagnostic procedures, and often subjected to pacemaker implantation for what are, in fact, slight variations of normal.

(4) The "sick sinus" syndrome seems to be the source of a great deal of abuse. It is now clear that the sick sinus syndrome does not present a threat to life per se; in other words, nobody dies of it as a primary entity. About the only hazard from a sick sinus or inadequate sinus syndrome comes if the patient becomes excessively dizzy or loses consciousness while operating a vehicle or a heavy piece of machinery. Thus, the hazard is secondary to the patient's occupation, and only when symptoms are clearly defined, definitely related to subnormal sinus node function, and distressing or incapacitation, is pacemaker insertion justified. The same comment applies for those cases in which electrical testing elicits some degree of abnormality of sinus node response—in other words, since this syndrome is not, per se, a threat to life, pacemaker insertion is only justified if symptoms are distressing or incapacitating and if they are clearly related to subnormal sinus node function.

(5) New or nonexistent disease entities have been invented to justify pacemaker insertion. The ventricular ectopic beat, or "skipped beat," is a common phenomenon which most people experience at one time or another. These beats very rarely require treatment; about the only clear-cut need for treatment can be shown in the acute stage of a heart attack or in the period immediately following it. There is some evidence that very complex, frequent forms of these beats may require treatment, but even this has to be considered experimental. A kind of tortuous logic is used to justify pacemaker insertion in these people: First, the patient is told that the extra beats, or ectopic beats, require treatment (when, in fact, they do not). Second, the patient is told that the drugs that suppress these beats may slow the heart rate dangerously. (This is not usually the case; as a matter of fact, the drugs used to suppress these ventricular ectopic beats may be perfectly well tolerated in a great many cases.) Before this drug is even tested to see if it does produce slowing, the patient is told a pacemaker must be inserted to permit treatment of the ectopic beats (which, of course, didn't need treatment in the first place. The word "tortuous" is a mild one to apply to this kind of rationale).

"Chronotropic incompetence" is a phrase coined to describe a nonexistent clinical state in which the heart is beating too slowly for the needs of the patient, even though the sinus node and all elements of the conducting system are functioning normally. The presumption here is that the patient will "feel better" if the heart is going faster. In fact, simply running the heart at a more rapid rate with an artificial pacemaker does not increase the amount of blood pumped per minute; the heart works on a feedback system to the arteries of the body and, within a considerable range, pumps the amount responded. If one speeds the heart rate artificially with a pacemaker, the amount of blood per beat simply falls and the total output remains the same. I asked 15 of the leading authorities in the world in the field of cardiac arrhythmias and electrophysiology if they had ever heard of the syndrome of "chronotropic incompetence" and I was met with blank stares and incredulous questions as to what I was talking about. Despite all this, this kind of imaginary syndrome or disease state is evoked to justify pacemaker insertion in a number of patients with slow heart rates with nonspecific or minor symptoms. Unbelievably, during sworn testimony in Pima County, a cardiologist asserted that "any older patient who describes a sense of fatigue and has a slow heart rate will benefit from an AV sequential pacemaker."

In other words, while there are a few well-defined, clear-cut reasons for inserting pacemakers, the abuse has arisen from the fact that many physicians simply are not well trained in the recognition and evaluation of cardiac arrhythmias, and they persist in attributing undue significance to what are, in fact, minor variants often well within the range of normal. Thus, most patients' pulses will slow to the rate of 40 or 50 beats per minute during sleep, since the body's demands are very low at that time. This entirely normal phenomenon of nocturnal slowing again has been cited

as evidence of subnormal function of the sinus node and as justification for insertion of a pacemaker.

It is a lamentable fact that in the medical profession, controls have had to be instituted to prevent abuse in every aspect of surgical or invasive procedures. Thus, tissue committees exist in every hospital to review appendices, gall bladders, and other tissues removed, and to make sure that the surgeon's diagnosis was justified. If a surgeon persists in removing normal tissues, his staff privileges will quite properly be suspended. This kind of review obtains in all fields of surgical and obstetrical management. Unfortunately, in such fields as cardiac catheterization, coronary bypass surgery, and pacemaker insertion, there are no tissues to study to see if the procedure was justified, and the assessment lies purely in the judgment of the operator. Unless stringent, conscientious peer review standards are promulgated, there will predictably be abuse, and experience today suggests that this abuse has taken place on a very large scale indeed. The committee may have a great many more questions of a more technical or specific nature, and I will be very glad to try to answer them.

Senator HEINZ. Thank you very much, Dr. Phibbs, gentlemen. Although I was absent, Dr. Furman, for your testimony, I have read it. It is absolutely outstanding. You are clearly one of the experts in the field. I might add that the committee is very grateful to you for all the assistance, not only today, that you have given us over these weeks and months while we have been conducting our investigations.

You have just heard the testimony of Dr. Kowey and Dr. Phibbs concerning the overutilization of pacemakers, the maladministration of pacemakers. Dr. Kowey estimated that perhaps, on the average, one-third of the pacemakers that are inserted should not be inserted.

In your opinion, to what degree are pacemakers overutilized?

Dr. FURMAN. Senator Heinz, first let me thank you for your kind remarks and then try and answer your question. I must say that I have not seen the kind of major local problem to which Dr. Phibbs has referred. That may be because I am not so much involved in local observation of other people's efforts. It is my impression that of those people who are referred to me in consultation who have had a pacemaker implanted, that well under 10 percent have had the pacemaker implanted for indications with which I would disagree.

Further, we are frequently called upon to treat a patient with a condition resistant to all of our efforts at control. There are many times when I dispute with colleagues at my own institution about whether a particular patient requires or will benefit from cardiac pacing. Sometimes I acknowledge that they are correct and implant the patient. Other times I am persuasive and do not implant. Still others I may point out that a specific condition is suitable for pacemaker management, even if they had not previously considered it. But all patients meet my approval and I am the "gate" through which all potential pacemaker implants must go, at my institution.

Senator HEINZ. Every so often, we run into that around here, for some reason or another.

Dr. FURMAN. Well, I am delighted to hear that that occurs.

I think the studies of whether cardiac pacing is done inappropriately in a special area or in general should be done the studies in every other area, carefully, and with an immense amount of time and effort. Those studies should be performed, should be written,

should be analyzed, and should be presented to the medical community. I think that is a very, very important consideration.

There were several studies referred to in the Health Research Group report, including one study of my own about costs. I have a copy of that available, should anyone want to see it. There are several other studies. One is the Boston study of 1979. It was presented as an abstract in 1979, in a format which is not reviewed critically. That is, if the abstract is submitted, it will be published with the attitude that everything should be seen and discussed. I have never seen a manuscript. I have read about it in Barron's, I have read about it in the Health Research Group report. I have never seen a manuscript. I know from seeing the Health Research Group report that it has been submitted and is under review in the journal, Lancet, one of the outstanding journals in the world. But "under review" means that Lancet reserves the option to say, "Not good enough." I would like to see that manuscript. I would like to look at the details. I would like to have more than 100 words saying, "We saw 10 people who were inappropriate, and if you multiply 10 by the fraction they represent of all the patients we saw by the cost of the units, why, you get this number."

The second report, the Health Research Group report, also represents a problem. It is traditional and well known that if all one studies is the face sheet of a patient's chart, that very little information is derived and that information should be used only as a guide to reviewing of the chart.

The president of the ICHD in the United States, and my boss on that committee, is Dr. Leonard Scherliss, who is professor of medicine and chief of cardiology at the University of Maryland. He is the current president of the Maryland State Society of Cardiology, and a member of the executive committee of the Baltimore City PSRO. Scherliss decided to undertake a chart review in his various capacities, of those people who failed the Health Research Group criteria. They went through a complex mechanism of obtaining permission from executives at the various hospitals and the appropriate doctors in order to review charts themselves. The report of the chart review is not complete, but Dr. Scherliss called me yesterday evening, here in Washington, and described a variety of findings during the chart review. First, that commonly, the correct diagnosis was written in and coded incorrectly, and it is the code that runs the computer. Second, that frequently there are more than five final diagnoses on one face sheet. The computer pulls up only the first five. If the indication for pacemaker implant is diagnosis as six or seven, it will never be seen.

Third, temporary pacemakers, that is the insertion of a pacemaker during an acute illness in which the permanent unit is not implanted, were commonly miscoded for a permanent pacemaker. In one case, a phrenic nerve pacemaker, that is, an electrical device used very infrequently, for stimulating respiration, was coded in the record room as a permanent implanted cardiac pacemaker, clearly a different technique.

One major area was that of a very irregular beating of the upper heart chambers, the atria, which is sometimes associated with a very slow response of the pumping chambers. We call that atrial fibrillation with slow ventricular response. All of those diagnoses

were coded in the computer as atrial fibrillation only, which in itself is not an indication for cardiac pacing.

He had reviewed 135 of the charts by the time he called. There are, I guess, some 500 or 600 charts at issue. He told me that the people who are cooperating in the review had found only two that were questionable.

"Leonard," I said, "that is a low number."

He said, "That is the number we came up with."

And then, he asked me to read a sentence which I questioned three times. "Do you really want me to read that?" and three times, he said, "That's what I want you to read." So, if I have your permission, "In the opinion of Dr. Leonard Scherliss, who has reviewed the data of 135 consecutive reports, based on chart review, the Health Research Group report as written is naive or stupid or malicious or most likely, a combination of all three."

And after he read that to me, and I copied it down as he said it, I once again said, "Leonard, are you sure, because I will read it if given the opportunity, and I will quote you." and he said, "Yes, I am sure."

Senator HEINZ. You have also made a number of disclaimers which are duly noted.

Dr. FURMAN. Well, I did not review those charts personally.

Senator HEINZ. That fact is duly noted. Do you have some more to say on this point?

Dr. FURMAN. No.

Senator HEINZ. My time has expired, and I want just one brief followup question. You are seeing, you say, about 10 percent——

Dr. FURMAN. Or less.

Senator HEINZ [continuing]. Or less—malutilization. Dr. Kowey is estimating roughly one-third. Dr. Phibbs examined, what, 24 instances and found maybe 4, maybe 7, where the indications were right, which is 70 or 80 percent malutilization.

Let me ask you gentlemen this. Why is there such a difference, not only between your own numbers, and there is a big one there, but between yourselves and Dr. Furman? Answer the latter question first, if you might.

Dr. KOWEY. I firmly believe that the difference between the statistics that are being quoted is simply a sampling problem, which relates to the fact that if one goes into a university hospital in which there are trainees, residents, fellows, and physicians who are very interested in pacemaking, that those patients seen in those hospitals are not going to receive pacemakers for unnecessary indications. And I think that this study from Boston University which—I think Dr. Furman has to acknowledge the fact that there are studies from other centers besides the one that he has criticized this morning——

Senator HEINZ. So you are saying that because Dr. Furman is at a teaching hospital—Montefiore is a teaching hospital, I assume; is that correct, Dr. Furman?

Dr. FURMAN. Yes, it is, but I did not recognize my hospital in Dr. Kowey's description. I did not recognize the statement you made regarding the study from Boston in which Dr. Paul Levine, the senior author, disclaimed the interpretation you put to it in the dis-

cussion following its presentation. He simply described significantly different practices, but not that one was better than the other.

Senator HEINZ. Well, let us allow Dr. Kowey to proceed.

Dr. KOWEY. I wanted to point that out as an issue. There are a couple of other issues, I think, that relate to the specific issue of unnecessary pacemakers. One is that we are implanting a significant number of pacemakers in this country, more per capita than other developed Western countries such as the United Kingdom and Canada, in which sophisticated medical care is rendered.

I would also like to point out that we have also conducted a chart review in our hospital in which we found a very good concordance between the discharge diagnosis and what was rendered in the chart as being indications for pacemaking, and I would like to see the report that Dr. Furman is quoting, as vigorously as he would like to see the paper that we have, presently being reviewed by "Lancet." I think that this is a legitimate difference of opinion regarding the incidence of unnecessary pacemaker implantation.

I would simply reiterate that there are a number of studies that dealt with this issue which seem to be coming up with a reasonably consistent set of results, which is, that about a third of the pacemakers are unnecessary.

Senator HEINZ. Dr. Phibbs.

Dr. PHIBBS. I agree. I think it is a matter of sampling. At our university hospital in Tucson, we found unexceptional indications for every insertion. There were no bad calls. However, one hospital in Phoenix, I would say you are over the 70 percent inappropriate insertion level. At another one, it changes to under 10 percent. It is a very spotty phenomenon. But there are some centers that are referred to by cardiologists as "pacemaker factories," where people are generating enormous incomes, at $1,000 per insertion, putting them in for indications that would be considered unacceptable by any standard in the world. And I am quoting most authorities in the field of arrhythmias, which is what I have written a textbook about, cardiac arrhythmias, men in five universities that I can name, that have looked at this problem.

Senator HEINZ. Dr. Phibbs, thank you.

Dr. Furman, before I yield to Senator Chiles for his questions, do you have a brief response?

Dr. FURMAN. Very brief. Only that we are all in favor of studies. I simply believe that we should take the opportunity to structure a study on a very large basis which will take in a large number of pacemaker implants and also provide benefit for the public, as well as settling this issue. This is an issue of professional indications, and I think this forum is not the place to resolve them. These papers have to be worked on, presented, and then perhaps we can get something out of the analysis.

Senator HEINZ. Thank you, Dr. Furman.

Senator Chiles.

Senator CHILES. Well, do you all agree that there should be some standards? Do you, Dr. Furman, agree?

Dr. FURMAN. I certainly do. I spend a lot of time preparing them.

Senator CHILES. What I am trying to elicit from you and from the panel now, is what we should be doing now. We have got a good, juicy hearing going now, but what should we be doing to try

to see that we correct some of these things? You have mentioned the registry. You think that there should be a national registry?

Dr. FURMAN. Yes; I think that would be a superb idea. It would provide real, individual patient benefit. The manufacturing community would know when they are having some problem; the regulatory community would be aware of any problem going on; and doctors would have access to overall figures.

Senator CHILES. Then we should require that the warranty also cover medicare, as well as the patient and the doctor, should we not, if we are having a warranty?

Dr. FURMAN. Certainly.

Senator CHILES. I mean, if we are paying for it, the taxpayer is paying for it.

Dr. FURMAN. Of course.

Senator CHILES. And the registry would certainly help to be able to monitor the warranty and to see what we were doing there. And then again, on standards, is there anything else that you see as action that we should be taking now?

Dr. FURMAN. No; that is about it. But I must tell you there is a disincentive for many institutions, for example, to really chase after the individual warranties. My own institution, for example, has one-quarter of a billion dollar a year budget. Even though we are very active in cardiac pacing, pacemakers represent another nuisance financially. In my institution, warrantee reimbursement is carefully sought.

Senator CHILES. But as long as Uncle Sam is going to pay it, there is certainly going to be that disincentive, is there not?

Dr. FURMAN. Absolutely.

Senator CHILES. If Uncle Sam says, "We won't pay," then there is a little incentive to hold down costs, is there not?

Dr. FURMAN. There certainly is, that is correct.

Senator CHILES. Dr. Blum.

Dr. BLUM. Well, there are a couple of comments that I have thought about over the period of time about this sort of thing, and maybe this gentleman will agree with me. I come from a community that does not put in thousands of pacemakers a year, and it seems as though in that microcosm that the people who might be vulnerable to offers of trips or money under the table are also the ones who have a questionable indication for putting in pacemakers. I cannot say that specifically on any individual, because it has not been studied that tightly in our community even. But when you do talk about things which allow extra money to come in, when you do talk about being able to be reimbursed for procedures through medicare in a degree that is a bit out of proportion to the amount of work required, and when a hospital can reap a substantial reward for having a pacemaker put in, it does have a tendency to increase the amount of abuse by individuals who might be so inclined. Just terminating those particular things could be helpful.

Senator CHILES. Thank you, sir.

Dr. Kowey.

Dr. KOWEY. I think that there is a movement afoot within the medical community to begin to look at these issues very carefully and critically. I think there is evidence in a recent New England Journal of Medicine article, an editorial and letter published on

July 15. There has been a resurgence of interest in looking very critically at this issue of whether or not we can make decisions about necessary or unnecessary pacemakers. I think that it is clear to most people who are working in this area that there is a rate of unnecessary pacemaker implantation, and whether it be at 10, 50, or 70 percent, I am not sure at this point. But I think that it is clear to most of us who are working in this area that there is a problem. Now, the next question is how to approach it. I think that obviously, we need better education for physicians and better regulation. Specifically how that should be done is something that I think we need your help with, as well as the other way around.

Senator CHILES. Dr. Phibbs.

Dr. PHIBBS. Specifically, Senator, you are saying what can you do in this context now, in practical, pragmatic terms?

Senator CHILES. Yes.

Dr. PHIBBS. I have a couple of suggestions.

I have been a physician for over 40 years. I have been president of a county medical society, chief of staff of a hospital, and on the faculties of three different medical schools. I have had a pretty good look at the spectrum. I am going to make a statement that has no exceptions; we cannot often do that. Any procedure that generates substantial profit will be abused by a minority, an unscrupulous minority, of this profession, maybe any profession. It has always, without exception, been necessary to set controls.

I was in on the formation of a tissue committee. If you go to a hospital and have your appendix removed, that tissue has to be removed now, by regulation. And if it was not a diseased appendix, the physician is called on the carpet by something we call a tissue committee. If he is too much out of line, he will have his privileges revoked. It has been necessary to have this kind of review in absolutely every area, certainly, of surgical or invasive intervention. There have been no exceptions.

The field we are talking about now calls for the same kind of review, but there is no tissue to take out. We cannot say, "Charlie, you took out a normal appendix. How do you explain it?" So, we need standards.

There are gray areas, as Dr. Furman indicated, but they have narrowed down enormously with new research information. And you can get about a 95-percent consensus on legitimate indications and what are not. In southern Arizona, we convened a committee of the chiefs of cardiology at the hospitals, including the faculty of the university. In 2 hours, we were able to outline good standards. These were promulgated, circulated, to all of the physicians in the southern part of the State; their comments were received, solicited, they were recirculated, they were accepted; there was no problem about it, and we substantially solved that problem. I suggest vou can do the same thing.

Senator HEINZ. Thank you, Senator Chiles.

I would just like to observe that we have identified three problem areas, have identified solutions to two. The three areas are: utilization; second, the problems of replacement and warranties; and third, the one we have identified today in addition to those is the overall cost of the program relative to what people are getting. And it has been suggested with respect to overutilization that we

need indices, we need standards, and indeed, such is recommended in our report. With respect to replacement, Dr. Furman has recommended a registry and changes in the way the warranty operates. Again, that is, I think, well worth doing and looking into. But the one area we have not really touched on is, are we getting what we are paying for, even after we do those two things. And it has been said that this procedure has changed a lot over the last 20 years or so, that it is no longer the frontiers of medicine that it once was; it is not the great risk today that it once was; it is not as long and difficult a procedure as it once was. Yet, medicare pays as if it was still in the early days.

Dr. Blum, you have been implanting pacemakers for a very long time, over 20 years, I understand. How would you assess medicare's payment for these procedures?

Dr. BLUM. Well, just under 20 years.

Senator HEINZ. Excuse me.

Dr. BLUM. Well, there were some questions asked by some of the Senators and some of the other comments before we came up here, but let me give you some ideas of maybe what is happening, at least in the community in Colorado, and I know that other areas are a little bit different.

One of the things is that in our particular system, where medicaid and medicare are handled through Blue Cross and Blue Shield, there are some guidelines in terms of establishing what the costs would be. One of the Senators mentioned that this was dating back to the thorachotomy times. Well, to give you an idea, let me say this. A pacemaker put in by a thorachotomy if one were to be done today in my area of the country would cost $1,200, approximately, as far as the surgeon's fee is concerned. A pacemaker with the so-called transvenous electrodes, or the ones that are most currently put in now and actually, most of the time, would generate a price of $1,080 roughly.

Now, part of the problem is that that $1,080 is based on a figure that did date from the early times when transvenous pacemakers were first put in, and at that time, the technology was not such—the pacemaker companies were producing leads which were far more difficult to get in the proper location; it could take 2 hours, easily, at times; it was not necessarily a 30-minute procedure, and there were a few little tricks that you had to learn in order to get these bloomin' things even in the vein and down into the heart.

In the last 4 or 5 years, a whole host of things have changed: The technology of those particular leads, not just the pacemaker itself; the ability to insert them through an opening made into a vein with a needle, rather than trying to cut down or sort out a vein which could be difficult at times, changed the situation so that while this $1,080 or relative value of that 10 years ago, or 5 years ago, even, would have been appropriate, what several of my colleagues and I have done in our particular community is to have cut that in half, if we are able to do it, in the 10-, 15-, or 20-minute procedure that you are hearing about all the time. If you can do it that way, we have been cutting our fee in half, because it does not require the extra work. It does not require the——

Senator HEINZ. So, the Department of Health and Human Services today could save a lot of money just by making a careful deter-

mination of what in fact is a reasonable cost, based on changed procedures. Apparently, they have not done so. What you have done is you have not waited for the Department of Health and Human Services. You have reviewed the procedure, and voluntarily cut your costs to medicare in half.

Dr. BLUM. Well, myself and several of my colleagues who are surgeons have found that the cardiologists in the community—not to a man, but on a couple of occasions—not only charge the current bill of $1,080, but actually doubled it for—how do they put it—cardiac evaluation, afterwards. But the point is, for the insertion of the pacemaker, regardless of who does it, it is a different matter than it was 5 years ago, even if it was via transvenous means——

Senator HEINZ. Dr. Blum, in fairness to Senator Durenberger, I did not know I was going to get as technical and complete and thorough an explanation—I do not fault you for giving it—as I did, but I am infringing on his time.

Dr. BLUM. I am sorry.

Senator HEINZ. It is not your fault, it is my fault. But this is not an inappropriate lead-in for Senator Durenberger, because we are still dealing with the present system of so-called reasonable cost reimbursement, and I know his interest in trying to do something going beyond that.

Senator Durenberger.

Senator DURENBERGER. Let me take up where you left off, then. You made the comment, Mr. Chairman, that this is something HHS ought to get involved in. I am a little bit leary about having HHS move in very quickly and start setting a minimum or maximum fee standard. I am more interested in what I have heard from several of you about peer review and the value of peer review. For 2 years now, the administration has been telling us that PSRO's are no good, they are regulatory, and we ought to get rid of them. Then the American Medical Association congregates wherever they do and has a close vote saying, "We are against peer review, too." And despite all that, we were successful in amending the peer review process. I would just like your comments generally, particularly as it relates to what we are talking about today, about the value of peer review.

Dr. KOWEY. Let me just make the point again—and again, it is in my statement—the paper that was published by Chokshi and Friedman, which dealt with peer review at the Brooklyn Hospital, I think is a very important paper and one that I do not think has gotten as much mention as it should. It really did dramatically reduce the number of pacemaker implantations, and it was a very casual committee. It was not the kind of thing where they were going around, beating on doctors' heads and telling them not to put pacemakers in. In was a committee that reviewed pacemaker implants after they had been performed. And the number of pacemaker implants dropped dramatically, especially in those categories for implantation that I think most people who work in this area would agree were questionable—at least questionable, if not outright unnecessary. I do not think it has to be a very elaborate ordeal to set up a review panel within a hospital, or within a medical association, but I do think that this is an issue that physicians have to deal with. We cannot expect the Government agencies or

anyone outside the medical profession to help us with this because, as I said earlier, these are issues that only physicians can deal with, and they are complex issues, in pacemaking and arrhythmia.

I would think that this is at least an idea which needs some more investigation, especially given what has already come before in terms of research.

Senator DURENBERGER. Dr. Furman.

Dr. FURMAN. To every benefit, there may be some difficulty. Let me describe some of the effects of the local PSRO in our area.

We now deal with a relatively defined hospitalization period for the implantation of pacers; each hospitalization is legitimized by what is done during that hospitalization. If a pacemaker is implanted, that is the visible result of the hospitalization, even though an awful lot of thinking may have gone on. The PSRO may allow 4 days for that procedure. So the pressure now, if a patient is admitted to the hospital with in-hospital diagnostic procedures required, is to move very rapidly and sometimes in unreasonable haste, simply because we know that the chart is going to be reviewed, and the legitimacy of the duration of the hospitalization will be based simply on the end result—an appendectomy, a pacemaker, or whatever it happens to be. So that is not too good.

Second of all, peer review is, of course, an excellent idea in general, but it is entirely possible in a peer review committee in a specific institution simply to stifle whatever evolution, development, and progress is going to occur.

The United States is today the leading country in the world in medical comprehension and technology. The medical journals that are read around the world are not in French, not in German, but in English. They are not in British English, by and large, but they are in American English. I would hate to see us throw out the baby with the bathwater. I think that we must be very careful in whatever regulation, whatever peer review, whatever controls we place. Yes, they should be placed; yes, we must look carefully. But yes, also, we must define techniques which preserve both the best attention for the public and also, the best level of progress, because that surely is good for the public in the end.

Senator DURENBERGER. Dr. Phibbs.

Dr. PHIBBS. I am the chairman of the PSRO cardiac committee for southern Arizona, so what you are saying is very much to the point where I am concerned.

I want to amplify what Dr. Furman said in two directions. First, the PSRO's have been concentrating on a minor aspect of cost containment; that is, the length of stay. You have some computer people and statisticians saying that the median stay for pneumonia is 4.265 days and you are over by 2.4 percent. That is not where you are losing your money. As Dr. Furman said, if you have a pacemaker, you have to be in 4½ days. That is not the question. The question is whether you needed a pacemaker at all. And we worked with our PSRO, and they turned their attention to invasive cardiology, did the patient need the coronary arteriogram——

Senator DURENBERGER. Appropriateness.

Dr. PHIBBS. Right. And it worked. And it is not that hard to do among men of good will.

Second, I think, when we say "progress," we have to distinguish between research and application of acknowledged therapeutic benefit. If you want to do research on somebody, you go to the human subjects committee, and you go to the patient and say, "You have something—I do not know if this will help you. You are in a series. We are going to randomize"—all the rest of the scientific jargon. It is very legitimate in the proper setting at a research center, like your hospital, like our university hospital. On the other hand, for the man in clinical practice to say to you, "You need this pacemaker," on the basis of some research speculation, you see, is quite inappropriate. And there again, I think an adequate peer review system can make that distinction without too much trouble. But you need to put your peer review effort where the money is, literally.

Senator DURENBERGER. I guess the second question, given the time, is the whole issue of price competition among physicians and whether or not that plays any role at all. Clearly, I enjoyed Larry Pressler's question about the free enterprise system, but the answer to it, of course, is that any market in the free enterprise system behaves the same way. The buyers and sellers are going to behave the way they are rewarded to behave, and obviously, one of our problems here is that there are no rewards for good behavior unless you have good public servants, like Dr. Blum and others.

But I wonder if any of you have any evidence that prepaid plans might do a better job with price sensitivity than the current fee-for-service system. Can you see in HMO's or IPA's or other alternatives some more appropriate behavior? Also, if any of you have given any thought to moving the reimbursement for implantation from part A to part B, thereby putting the burden on the physicians, I would appreciate your comments.

Dr. FURMAN. I am not quite sure I understand that question. Do you mean have the physician pay for the pulse generator out of his billing?

Senator DURENBERGER. Have the physician control the payment for the procedure by including it in part B.

Dr. FURMAN. Aside from the fact that it would add an immense complexity to the physician's practice, I think that it would be far more open to abuse than the situation which exists today, at least from my point of view.

I am now responsible for the patients in my medical practice, academic activities, teaching, and supervision of house staff and technical staff. I am responsible for billing for the practice and the academic activities. I would be horrified to be responsible, in addition, for purchasing and billing for each piece of hardware. As a salaried hospital employee, I do not earn more if I work harder, so I want to avail myself of hospital staff to purchase equipment. On a national level, purchase of pacemakers by physician users would open up a far greater possibility for abuse than exists now.

Dr. KOWEY. I just wanted to key on what Dr. Furman just stated about the fact that he is salaried, and I want to get to the issue that most physicians who work in university hospitals are, in fact, salaried and not paid on a fee-for-service basis. It gets back again to what we talked about, which is the fact that the abuses tend to

exist not in the university hospitals, but in the community hospitals where fee-for-service is usually the method of payment.

I want to just ask you, is it a possibility to have the hospitals more responsible for paying for sophisticated medical devices for their patients, rather than always turning the billing over to the medicare people, which is basically what we are doing now—a per capita charge, or an HMO-type style, might make that hospital more cost conscious in terms of taking care of the patient who is——

Senator DURENBERGER. That is why I asked that last question: who chooses the hospital? It surely is not the patient.

Dr. KOWEY. No. That is right.

Senator DURENBERGER. It is the physician. The physician is clearly in the best position not only to determine appropriateness, but to leverage the costs and the facilities that he uses to provide the service.

Dr. KOWEY. I must agree with Dr. Furman. I think that that would be a tremendous responsibility for the physician, a very big responsibility for a hospital, but almost impossible for the physician.

Dr. FURMAN. Senator, I just returned about 3 weeks ago from a month in Great Britain. I must tell you that much as we are concerned about overutilization and cost, the constant topic on BBC at the time was the underavailability of medical attention under the national health service. They are at least as concerned as we are. Having spoken to people concerning the incidence of the implantation of cardiac pacemakers, they have emphasized, "Well, look, if you run out of budget by the end of the year, that is it."

And I said, "What? What is it? What happens?"

"Well, you beg one, you borrow one, you steal one. Sometimes a patient does without."

Senator DURENBERGER. But that is where we have been headed in this country. When hospital cost containment first came along, that was the proposal: "There are only x number of dollars." Now, that has been replaced with a medicare budget that the Congress decides it is going to cut by $14.5 billion. And that aims us in the direction of, in effect, rationing care. And that is why a lot of us keep coming back to who determines how sick care is going to be delivered in this country, and who ultimately decides both the appropriateness issue and the cost issue, and it is the physician.

Now, the question that we have to deal with, of course, is how, in the long run, do we put together the appropriate mix of the consumer who has the need and the physician who determines and analyzes that need.

I hope I leave you with the notion that this is a larger problem than just setting some standards and getting HCFA too involved in the process.

Senator HEINZ. Thank you, Senator Durenberger.

Senator Glenn.

Senator GLENN. Thank you, Mr. Chairman. Before asking questions, I would ask that my prepared statement, which I was unable to give at the start of the hearing, be included in the record.

Senator HEINZ. So ordered.

[The prepared statement of Senator Glenn follows:]

PREPARED STATEMENT OF SENATOR JOHN GLENN

Mr. Chairman, I commend you for calling this hearing on "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry." I hope that today's hearing and the committee print we are releasing will result in action to eliminate the current widespread problem which may be costing medicare $1 billion per year in illegal and unnecessary payments.

I was appalled to learn that medicare reimbursements are paying highly inflated costs for pacemakers to hospitals; that perhaps 30 to 50 percent of all pacemaker implants are unnecessary; that medicare lacks a systematic process for tracking pacemakers replaced within warranty periods and assuring warranty credits are used to offset future medicare costs necessitated by the replacement; that payments for pacemaker monitoring appear outrageous; and that evidence of kickbacks, consulting fees, rebates, and other improper inducements to do business has existed for more than 5 years.

The Aging Committee's investigation has found that most of the abuses present in the pacemaker industry are well-known and of long standing, and that a key to the abuses lies in the relationship of the physician and the pacemaker salesman. The problems related to the purchase and use of pacemakers for medicare beneficiaries—performance, cost, warranty, professional qualifications of implanting physicians, utilization, and allegations of criminality—have been identified by the Aging Committee's investigation, but also by previous investigations of the Securities and Exchange Commission, the Federal Trade Commission, the Veterans Administration, and the General Accounting Office. We know the problem. Now is the time for the Federal agencies involved to coordinate their efforts to address these problems.

We are all well-aware of the need to reduce Federal spending, and the administration has proposed cutbacks in medicare, some of which have been enacted into law, that increase out-of-pocket health care payments for the elderly. I suggest that the administration should increase its efforts to reduce spending by eliminating waste, fraud, and abuse in our Government programs.

Senator GLENN. Has there been this kind of abuse ever since we have had pacemakers, or has this been a growing problem?

Dr. BLUM. Which kind of abuse are you speaking about?

Senator GLENN. Well, the greed, I guess, is what we are talking about—the overcharging and the kickbacks. Is this something that has been with us ever since we have had this equipment?

Dr. BLUM. Well, I do not know that I can speak for everybody here, but at least in the neck of the woods that I have been working in, nobody has wanted to fiddle with them. Five and six and ten years ago, it was difficult to get them in in an appropriate period of time, and it was a lot more bother than it was worth for most people. You had a hard time finding anybody else that would even work with you on it.

So, no, it has not been that kind of a problem until, oh, about 5 or 6 years ago, when all of a sudden, there were 10 or 11 companies with a space-age technology that were all trying to get on, I think—and this is speculation on my part—and acquire a whole little world for themselves.

Senator GLENN. Estimates are that there might be as high as 50 percent unnecessary implants. How much of this might be 20–20 hindsight, where at the time, it was the best medical judgment that these implants were necessary? Or has it always been unncessary—that is what I am getting at.

Dr. BLUM. I have trouble separating the three specific things that all hinge on this particular problem, at least, in the area that I am working in.

One, you do not get very many unnecessary surgical implants of anything—I do not care whether it is pacemakers or finger joints—unless you get a fairly extensive remuneration for your time spent,

in terms of something under the table or fees that almost, in my opinion, anyway, are at times out of proportion to the amount of work that you have to do. If you can do 15, 20, 30 minutes' work, and sometimes almost do it from across the room, and get the kind of fee that it might take me to replace an abdominal aortic aneurism, and maybe sweat bullets for 6 or 8 hours or 7 days, you are going to get a lot of people doing the former.

So 8 percent of the physicians in this country charge less than $600 to put in pacemakers. All the rest are sky high—when you can have hospitals who can generate $1,300 of income from a $6,000 hospital bill just by having the pacemaker pass through my hands.

Senator GLENN. I understand that.

Dr. BLUM. OK. Those three things, I think, if they are brought under some kind of control, you do not have the abuse.

Senator GLENN. Is there any study that you have done, along with the other studies here, of those who were considered for pacemakers and were told, "No, you do not need it," and did not get it, and died?

Dr. KOWEY. The study that I referred to that was published in the New England Journal of Medicine on July 15, dealt specifically with the issue of following patients who were deemed to need or not to need a pacemaker, and they followed them over a period of time to see whether or not those patients died. And in fact, what the study showed was that a very, very small percentage of patients who were thought to be in the "needy" category and did not get pacemaker implants, died.

And so, I do not have the statistics in front of me, but I think it was a very impressive study showing that even now, we do not really understand what the natural history of a lot of these disease processes are.

To answer your other question, Senator, I think that one of the things that has really revved the system in terms of pacemaker implantation is the technology that has gone along with it, specifically, Holter monitor technology, which is where you carry a box around, and you have all your heartbeats recorded for 24 hours. We never had the opportunity to Holter monitor people a few years back, and that has been something that has been relatively recent. And now we are seeing things on Holter monitor that physicians interpret as being an indication for pacing, that patients always had, had 10 years ago, had 20 years ago, but were never seen, were never recognized.

Senator GLENN. That is the reason I was wondering whether we are all smart now because of 20–20 hindsight.

Dr. KOWEY. No, we are not any smarter, Senator. What we are is we are just picking up things that were there before.

Senator GLENN. Dr. Furman.

Dr. FURMAN. Virtually any technology starts by dealing with the most difficult and the most obvious problem. I tried to point that out in my original statement. We are now at the point at which a physician is required to make the correct judgment under all circumstances. It must be remembered that there are many more questions, many more interpretations, many more oddities seen on an electrocardiogram and, especially, on a Holter monitor record-

ing, than we have the definitive answer for. If it takes a 5- or 10-year study, as described in the New England Journal article to which Dr. Kowey refers, it takes that number of years to get an answer. The evaluation often cannot be accelerated. But we are expected, at the time a patient appears before us, to do the right thing. You must understand that we are sometimes expected to know the natural history of a disease which is just being described. That is a legitimate request on the part of the patient, even though there is no answer. If we review a Holter monitor, that is, a 24-hour tape-recorded electrocardiogram in a patient who has had a fainting spell and in whom, apparently, all other indications have been removed, we may see a pause in cardiac function of 1 second, 2, 3, 4, or 5 seconds. That patient will then have a right to expect us to do not only what is right, but should we guess wrong, do something that will keep him alive. Sometimes, we really do not know the significance of that pause, but the pause is there, and we are held to the standard of knowing what it is and dealing with it in the best interest of that individual patient. It is not easy.

Senator GLENN. Just one other question. When greed is involved like this, and it has settled in one particular field, I wonder whether a Government regulation is going to really solve the problem. Won't we then find the problem having moved to bone surgery or heart bypass operations being quintuples instead of triples, or whatever. I think it is very difficult by Government regulation to control things when the Hippocratic oath turns hypocritical—I guess we could put it in those terms. And following up on Senator Durenberger's questions here, I hate to get into a whole series of Government-set fiats and standards that will just flip from one part of the industry, whether it is overprescription of pills, and you get a kickback from the pharmacy, or whether it is another thing. We will be forever trying to put our thumbs on quicksilver around here if we start trying to write a regulation for everything. It seems to me that much of this can come from peer review and maybe then Health and Human Services, working closely with peer review groups.

Just one very short question, if I might. Is your tissue committee something that was recommended—is this under a Government regulation or a peer-review regulation?

Dr. PHIBBS. That arose initially before there were peer reviews, Senator.

Senator GLENN. Is a followup on the tissue committee that you talked about a way of controlling this, that then could be in turn reviewed by Health and Human Services?

Dr. PHIBBS. Yes, the way the tissue committees are required for certification of any hospital. It has to be a certified hospital in order to receive Blue Cross or medicare or third-party payments. So it is not a Government statute, but it is an effective statute. You cannot be an approved, certified hospital without a functioning tissue committee, with records that can be reviewed by the reviewing body, which comes around every 2 years to look at your hospital.[1]

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[1] See appendix 2, item 1, page 132, for Dr. Phibb's fuller response to questions asked by Senator Glenn.

Senator GLENN. Thank you. My time has expired.

Senator HEINZ. Senator Glenn, thank you very much.

Gentlemen, you have been extremely helpful to the committee. You have made a variety of very constructive suggestions, and we very much appreciate your being with us.

Thank you very much.

Our last panel of manufacturers will be Whitney McFarlin of Medtronic, and Russell Chambers of Intermedics.

Gentlemen, will you please come forward? I understand you both have prepared statements. If you prefer to give them in full, by all means. If not, and you care to abbreviate them and keep them short, we will be sure that your entire statement is placed in the record.

I would like to call on Mr. McFarlin.

PANEL NO. 4. MANUFACTURERS

STATEMENTS OF WHITNEY A. McFARLIN, CORPORATE VICE PRESIDENT, PACING SYSTEMS GROUP, MEDTRONIC, INC., MINNEAPOLIS, MINN.; AND RUSSELL CHAMBERS, PRESIDENT AND CHIEF EXECUTIVE OFFICER, INTERMEDICS, INC., FREEPORT, TEX.

Mr. MCFARLIN. Mr. Chairman, my statement is about 6 or 7 minutes. I can shorten it a little, if you would like.

Senator HEINZ. Please, proceed.

Mr. MCFARLIN. Mr. Chairman and members of this committee, I am Whitney McFarlin. I am corporate vice president for the pacing systems group at Medtronic, in Minneapolis, Minn.

My responsibilities relate to the manufacturing, marketing, and sale of pacing products in the United States, and pacing research and development worldwide.

At Medtronic, we focus all of our energies on products and services designed toward helping people to a full life. We are in our 33d year as a corporation and our 25th year in pacing.

Why are we here to testify today? We are here because we were invited and because we want to present a balanced perspective of this industry. This morning, you have heard much about the problems of this industry. Let me state clearly that Medtronic does not engage in such abusive and illegal activities, and we as a corporation share your concern.

Another reason why I am here is that we are the leaders of this industry, and we feel a responsibility to lead. Because of this leadership position, we welcome the opportunity to state our position and emphasize our commitment to help people.

Now, what role has Medtronic played over these 25 years in the development of the pacemaker industry? We are the founders of this industry, and our story is typical of many American success stories. First, there was a need. Dr. Lillihei, a cardiac surgeon and pioneer in heart surgery, needed a way to restore normal heart rhythm in babies with complete heart block. From this need evolved external pacemakers, and ultimately, the implantable device. Medtronic, working with Dr. Lillihei and others, founded the pacing industry. We are the leaders today. We believe we have

the best products, the best services, and we are the most innovative company in this industry.

What improvements have we made in terms of reliability and safety of pacemakers over these intervening years?

We have increased the longevity of pacemakers from 18 months, 15 years ago, to in excess of 9 years today. We have enhanced the adaptability of pacemakers by developing the ability to adjust the pacemaker noninvasively, without surgery, to changing patient needs. Prior to this, surgery was mandatory.

Over this period, there has been a shift from what was once a major surgical process, opening the chest wall, or a thorachotomy, to a procedure that is performed today with local anesthetic. Needless to say, that dramatically reduces the morbidity and mortality of the elderly.

And, most significantly, we have freed people to lead a more normal life. People do not like to be handicapped. People want to be normal. And pacing allows active involvement, not passive involvement, in life.

We recently had a pacemaker patient run in the London Marathon, and that man is actively involved in life.

All of these innovations demonstrate the commitment that we as a company have for health care. What advances can we expect from this industry in the future? Not all of the inventions have been invented, and we need not close the patent office.

The next milestone on the road to full cardiac therapy is the treatment of rapid heart rates, or tachyarrhythmia. Last year in the United States, over 400,000 people died and 300,000 people were hospitalized with this disease. This represents a real human need that Medtronic is committed to fulfill.

Now, how cost effective is cardiac pacing? The real cost of pacing has declined dramatically over the last decade. The real cost of pacing is not the cost of the pacemaker, but rather, the cost per year of pacing therapy. Hospital and surgical time has been reduced; the need for reoperation has declined, and patient followup has been simplified. Previously, followup required a visit to a physician's office, which was not only more costly and inconvenient, but a chore for the elderly. Followup today requires merely a telephone call.

And then, most significantly is the value of returning people to productive roles in society. Our challenge for the future is not to keep people alive, but rather, to help people become productive citizens once more.

So Medtronic has worked and will continue to work not only to extend life, but to expand life to each person's potential.

How should we respond to the problems and potentials of this industry? There are many problems, and you have heard some of them these past 2 days—even illegalities. The answer to illegal activity is simple: Enforce the law, and punish the guilty. Many of the problems and practices in the industry today can be controlled by closer monitoring.

In the area of mounting cost, we encourage customer choice through increased awareness of the costs and benefits of pacing. We support current efforts to redesign the health care system to produce marketplace incentives for cost-effective health care. The

recent change allowing medicare patients to receive their care through health maintenance organizations was an important step in this direction.

The future has great potential, both for the pacing industry and health care as a whole. Price must be a factor, but I hope we do not become so preoccupied with price that we stifle continued investment and growth in research, development, and innovation. We must all work to help that pendulum swing to the middle and not the far extreme. We must strive for balance and help maintain the creative innovation that has made this industry significant in terms of saving and expanding human life.

Thank you.

Senator HEINZ. Mr. McFarlin, thank you very much.

[The prepared statement of Mr. McFarlin follows:]

Statement by

Whitney A. McFarlin
Vice President of Pacing Systems Group
Medtronic, Inc.

before the

Special Senate Committee on the Aging

PACEMAKER HEARINGS

Friday, September 10, 1982

Mr. Chairman and members of the Committee, I am Whitney McFarlin, Corporate Vice President at Medtronic. I head our Pacing Systems Group, which is responsible for manufacturing and marketing pacing products in the United States and for research and development worldwide. I am joined today by Stephen Mahle, our Vice President for Marketing, and Lawrence Shearon, our Vice President for Clinical Research.

We are here at the Committee's invitation. We appear this morning after discussion of improper sales practices that Medtronic deplores. While this behavior reflects badly on all of us in this industry, Medtronic's policy and our performance remain clear. Such practices are unacceptable to us. Rather than engage in them, we have walked away from some business, relying on our belief that the ethical judgment of the vast majority of physicians would support our decision. So we welcome the efforts of this Committee and others to bring about reforms in our industry.

But that is not the primary reason why we are here. You have asked us to address the broader issues facing an industry in which we have maintained leadership for over a quarter century.

Medtronic was founded 33 years ago to maintain and improve electronic equipment used by physicians in medical practice. Our focus remains on biomedical technology, and the physician remains our primary customer and colleague in research and development.

We are best known, of course, for our contributions in cardiac pacing. In 1958, Earl Bakken and Medtronic developed the first wearable, battery-operated external pacemaker. Two years later, in New York, the first clinically successful, self-contained, battery-powered pacemaker was implanted. Medtronic secured exclusive rights to

produce and market that device, thereby establishing itself as the founder of the pacemaker industry.

Since 1960, Medtronic and others in the industry, working closely with physicians who treat heart disease, have made continuing improvements in the performance, reliability and safety of pacemakers. Let me mention just three of these developments.

First, increased longevity. Longer-life batteries, energy-efficient circuits and improved leads have increased the average life of a pacemaker from 18 months fifteen years ago to about 9 years today.

Second, greater adaptability. Most pacemakers today can be adjusted without surgery. This means not only improved health care but also reduced costs whenever subsequent hospitalization and surgery are avoided.

Third, improved capability. Dual chamber pacing allows the pacemaker to reestablish the normal synchrony between the upper and lower heart chambers, permitting the heart to respond more effectively and naturally to the body's needs. As a result, the patient's well-being and capacity for activity are significantly improved.

Patients, of course, are the beneficiaries of these improvements. Pacemaker therapy has proven to be effective and safe for a wide range of cardiac conditions and rhythm disorders. For patients suffering from these diseases, pacing has made possible longer and more active lives. And, though the majority of pacemaker patients are elderly, they include people of all ages--from hours to a century old.

We think the opportunities to use pacemakers safely and cost-effectively will increase in the future. The primary use now of pacemakers is in the treatment of bradycardia (a slow or irregular heart beat). Increasingly, pacemakers will be used to treat very fast heart rates. More than 400,000 people died in the United States and over 300,000 were hospitalized last year due to this condition, known as tachycardia.

From the earliest years of the industry to the present, pacing has been a cost-effective treatment. Although the price of a pacemaker has increased as its capabilities have been improved, technological advances have caused the cost of pacing in constant dollars to decline dramatically. Data from a recent 15-year comparative study of cardiac pacing costs show that the total cost of treating the pacemaker patient dropped 43% from 1965 to 1980.[1]

So it is misleading to look only at the costs associated with the initial implant in assessing the impact on health-care costs of the changing technology in pacemakers. Both hospital and surgical time have been significantly reduced, re-operations have dramatically declined, and patient follow-up has been simplified. On a national scale, the increase in physical capacity to do work by today's pacemaker patient has major economic impact. We see such trends of cost effectiveness increasing in the future as new developments emerge from the laboratory.

Nevertheless, concerns have been expressed with respect to the cost of pacemakers and the cost to Medicare of pacing as a treatment choice. I would like to close with some brief observations about pricing and cost effectiveness.

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[1]Study by C. Langer, A. Lopman, S. Furman, D. Escher.

Health care policy over the last two decades has focused largely on quality and access. This has been particularly true for the elderly. Medicare was developed to improve the quality of the health care provided to persons over the age of 65 and it has done that. In fact, Medicare has had major impact on the quality of care provided to all Americans.

But there are limits to how much health care we can afford, and there is a growing consensus that the concerns and rights of taxpayers, consumers and providers must be balanced. We share with others involved in health-care delivery responsibility for addressing these issues.

In our judgment the solution must come through a redesign of the health-care economy along lines that more nearly replicate the traditional marketplace. As a member of the Health Industry Manufacturers Association, we have advocated this position. We continue to believe that only in a competitive environment that permits consumers to make informed decisions--taking into account both the costs and the benefits of the decisions--will health-care costs be controlled.

The inclusion in the recent tax bill of a provision permitting Medicare patients to receive their health care through HMOs was an important step in this direction. The requirement in that bill that a prospective payment plan for hospitals be developed by the HHS will provide another opportunity for the Congress to reorder the priorities and incentives of the current payment system. We are already seeing greater price sensitivity by many hospitals, and we expect more as a result of these changes. It is important, however, that price not become the only--or even the major--determinant in product choice.

Our goal for the future at Medtronic is to provide physicians and patients with the best products and services available. We want to conduct our business in an environment

where we can compete on the basis of product features, quality and reliability, on the service we provide, and on the prices we charge. And we want an environment in which everyone plays by the same rules. Fair and open competition based on these factors benefits patients, providers, and taxpayers alike.

In light of the problems that have been presented to this Committee, there may be strong pressures to change the way pacemakers are reimbursed. We would agree that reimbursement policy in some areas should be reviewed and perhaps altered. We would argue strongly, however, against changes that would make the system rigid and inflexible. For example, strategies designed simply to cap costs may not permit physicians to respond adequately to the varying needs of their patients. Such strategies would also focus inappropriately on the price of the pacemaker rather than on the total cost of pacing.

While price is important, even more important are the quality, reliability and product features of pacemakers. Physicians must have flexibility to prescribe the product most appropriate to the conditions of the patients they treat.

The cardiac pacemaker provides us a convincing example of how technological development can result in cost-effective treatment for large numbers of people. Through years of cumulative innovation, we have managed to reduce markedly the real costs of pacing treatment. As changes in health-care policy are considered, it is important that this environment of innovation, with flexibility, be maintained and nurtured.

Senator HEINZ. Mr. Chambers.

Mr. CHAMBERS. Thank you, Mr. Chairman.

My name is Russell Chambers. I am the president and chief executive officer of Intermedics. I am accompanied by the company's corporate counsel, Jonathan Golden of the firm of Arnall, Golden & Gregory, Atlanta, Ga., on my right. In accordance with advice from the committee's staff, I have prepared a written statement, which I request permission to read.

Senator HEINZ. Certainly. Please proceed.

Mr. CHAMBERS. Thank you.

I would also hope that I could make a few comments about some of the things I have heard, hopefully.

I am glad to be here to testify, and I am not one who is unhappy with being here. I volunteered to come, and I am pleased to be here, and I am pleased to answer any questions that you all can think of to ask me.

I did not receive your letter of invitation until Tuesday of this week, just 3 days ago, and yesterday at 3 p.m., I received the first copy of the information paper prepared by your staff. This report is over 200 pages long, as you know, and obviously, I have not had an opportunity to review it in any detail.

In my cursory review of the report, I must tell you that it is replete with errors, misrepresentations, and innuendos about our company, Intermedics, specifically, and our industry in general. Unfortunately, to the best of my knowledge, none of the accusations about Intermedics were verified with any Intermedics personnel, nor were any officials of our company questioned about information presented in the report or offered an opportunity to comment on that information.

We would respectfully request that the committee allow us the opportunity to review the report and file a written reply to the information report and have our response made a part of the record.

Senator HEINZ. Without objection, that request is granted.[1]

Mr. CHAMBERS. Thank you.

I urge you to take no action on the report until we and others have had an opportunity to respond.

Examples of accusations about Intermedics in the report that are absolutely false are the following. A key point of the report centers on the price of pacemakers. The cost of manufacturers to produce a pacemaker is cited as between $600 and $900. However, this standard cost figure does not include expenses related to research and development, selling costs, interest on bank borrowings, and a variety of other general and administrative costs. We could not build a pacemaker for that price, but given the fact that today's pacemakers will last upwards of 8 years or more, versus a 2-year life just 5 or 6 years ago, the cost of pacing has actually declined with advances in technology. The report fails to mention that distinction.

In terms of educational trips and programs conducted for implanting physicians, who, if not the pacemaker manufacturer, assumes that responsibility? Certainly not our medical schools. Training offered medical students during their university studies must

[1] See appendix 3, item 2, page 157.

be basic, and certainly cannot be expected to keep up to date with our industry's rapidly changing technology.

Another example of information in the report that implies that conduct by Intermedics is improper or possibly even illegal when, in fact, such conduct is neither is the following. The suggestion that providing equipment such as transmitters, programers, analyzers—and we do not provide analyzers—and the like without charge to a doctor is an improper enticement for the use of our pacemakers. Such equipment, in fact, is designed specifically to be used with our pacemakers and is loaned to the doctor so that he can program the pacer and monitor the patient. Without this equipment, he cannot implant a modern, sophisticated pacer. The equipment is not an enticement to the doctor, but a necessary tool for him to use our pacemaker.

I want to go on record here, as I have done in many other forums, that it is absolutely against company policy of Intermedics to engage in any activity that is illegal, improper, or unethical; and in particular, it is against company policy to make kickbacks, payoffs, or any other kind of improper payment to anyone in the medical industry or anywhere else. We just do not engage in those kinds of activities.

I would like to now make a few general comments concerning the recommendations the staff has proposed as part of their report.

The report indicates that the alleged problems have been investigated by the SEC, the FTC, the VA, and the GAO. If, in fact, the problems are so acute, we have seen nothing from these agencies indicating severe problems. Moreover, the staff has suggested that the DHHS consider a number of steps which we believe would reduce the effectiveness of the supply of medical services to the American public.

For example, the suggestion that pacemaker implantations be centralized in selected large hospitals similar to those employed for CAT scanners requires a great deal more study before any drastic step be taken.

The suggestion that explanted pacemakers not be returned to the manufacturer is absurd. How else can we determine how our pacemaker works and why a pacemaker appeared to be defective or ceased to operate, if we cannot disassemble it after explanting?

The suggestions and recommendations relating to the Food and Drug Administration are similarly misplaced, in my opinion. The American medical device industry is highly regulated. Before a new product can be brought to market, it must be extensively tested. Detailed clinical testing procedures are in place and as a result, America has the highest quality medical services available anywhere in the world today.

I wish we were in a position today to provide all of you with a more detailed analysis of the matters contained in the staff report and its conclusions. However, with having received the report late yesterday afternoon, it simply was not humanly possible for us to do so. With your permission, we will prepare and submit a written report as soon as possible.

In summary, I would offer that when news of this investigation became public in early July, I was quoted in the national news media as personally welcoming an investigation if improprieties ex-

isted. I also said that I had contacted the Government to offer my full and complete cooperation. That is why I am here today, and that is the way I feel.

Thank you.

Senator HEINZ. Thank you very much, Mr. Chambers.

[The prepared statement of Mr. Chambers follows:]

STATEMENT OF RUSSELL CHAMBERS
PRESIDENT, INTERMEDICS, INC.
TO
SENATE COMMITTEE ON AGING
SEPTEMBER 10, 1982

MR. CHAIRMAN, MY NAME IS RUSSELL CHAMBERS. I AM THE PRESIDENT AND CHIEF EXECUTIVE OFFICER OF INTERMEDICS, INC. I AM ACCOMPANIED BY THE COMPANY'S CORPORATE COUNSEL, JONATHAN GOLDEN OF THE FIRM OF ARNALL, GOLDEN & GREGORY. IN ACCORDANCE WITH ADVICE FROM THE COMMITTEE'S STAFF I HAVE PREPARED A BRIEF WRITTEN STATEMENT WHICH I REQUEST PERMISSION TO READ.

I AM GLAD TO BE HERE AND TESTIFY. HOWEVER, I DID NOT RECEIVE YOUR LETTER OF INVITATION UNTIL TUESDAY OF THIS WEEK, JUST 3 DAYS AGO, AND YESTERDAY, AT 3:00 P.M. I FIRST RECEIVED A COPY OF THE INFORMATION PAPER PREPARED BY YOUR STAFF. THIS REPORT IS OVER 200 PAGES LONG AND, OBVIOUSLY, I HAVE NOT HAD AN OPPORTUNITY TO REVIEW IT IN ANY DETAIL. IN MY CURSORY REVIEW OF THE REPORT I MUST TELL YOU THAT IT IS REPLETE WITH ERRORS, MISREPRESENTATIONS, AND INNUENDOS ABOUT OUR COMPANY SPECIFICALLY, AND OUR INDUSTRY

IN GENERAL. UNFORTUNATELY, TO THE BEST OF MY KNOWLEDGE, NONE OF THE ACCUSATIONS ABOUT INTERMEDICS WERE VERIFIED WITH ANY INTERMEDICS PERSONNEL, NOR WERE ANY COMPANY OFFICIALS OF OUR COMPANY QUESTIONED ABOUT INFORMATION PRESENTED IN THE REPORT, OR OFFERED AN OPPORTUNITY TO COMMENT ON THAT INFORMATION.

WE WOULD RESPECTFULLY REQUEST THAT THE COMMITTEE ALLOW US THE OPPORTUNITY TO REVIEW THE REPORT AND FILE A WRITTEN REPLY TO THE INFORMATION REPORT AND HAVE OUR RESPONSE MADE PART OF THE RECORD. I URGE YOU TO TAKE NO ACTION ON THE REPORT UNTIL WE AND OTHERS HAVE HAD AN OPPORTUNITY TO RESPOND.

EXAMPLES OF ACCUSATIONS ABOUT INTERMEDICS IN THE REPORT THAT ARE ABSOLUTELY FALSE ARE THE FOLLOWING:

A KEY POINT OF THE REPORT CENTERS ON THE PRICE OF PACEMAKERS. THE COST TO MANUFACTURERS TO PRODUCE A PACEMAKER IS CITED AS BETWEEN $600-$900. HOWEVER, THIS STANDARD COST FIGURE DOES NOT INCLUDE EXPENSES RELATED TO RESEARCH AND DEVELOPMENT, SELLING COSTS, INTEREST ON BANK BORROWINGS, AND A VARIETY OF

OTHER GENERAL AND ADMINISTRATIVE COSTS. WE COULD NOT BUILD A PACEMAKER FOR THAT AMOUNT. BUT GIVEN THE FACT THAT TODAY'S PACEMAKERS WILL LAST UPWARDS OF 8 YEARS OR MORE VERSUS A 2-YEAR LIFE JUST 5 OR 6 YEARS AGO, THE COST OF PACING HAS ACTUALLY DECLINED WITH ADVANCES IN TECHNOLOGY. THE REPORT FAILS TO MAKE THAT DISTINCTION.

IN TERMS OF EDUCATIONAL TRIPS AND PROGRAMS CONDUCTED FOR IMPLANTING PHYSICIANS, WHO, IF NOT THE PACEMAKER MANUFACTURERS, ASSUME THAT RESPONSIBILITY? CERTAINLY NOT OUR MEDICAL SCHOOLS. TRAINING OFFERED MEDICAL STUDENTS DURING THEIR UNIVERSITY STUDIES MUST OF NECESSITY, BE BASIC, AND CERTAINLY CANNOT BE EXPECTED TO KEEP UP-TO-DATE WITH OUR INDUSTRY'S RAPIDLY CHANGING TECHNOLOGY.

ANOTHER EXAMPLE OF INFORMATION IN THE REPORT THAT IMPLIES OR SUGGESTS THAT CONDUCT BY INTERMEDICS IS IMPROPER OR POSSIBLY EVEN ILLEGAL WHEN IN FACT SUCH CONDUCT IS NEITHER, IS THE FOLLOWING:

THE SUGGESTION THAT PROVIDING EQUIPMENT SUCH AS TRANSMITTERS, PROGRAMMERS, ANALYZERS, AND THE LIKE WITHOUT CHARGE

TO A DOCTOR IS AN IMPROPER ENTICEMENT FOR THE USE OF OUR PACER. SUCH EQUIPMENT, IN FACT, IS DESIGNED SPECIFICALLY TO BE USED WITH OUR PACEMAKERS AND IS LOANED TO THE DOCTOR SO THAT HE CAN PROGRAM THE PACER AND MONITOR AND FOLLOW THE PATIENT. WITHOUT THIS EQUIPMENT HE CANNOT IMPLANT A MODERN, SOPHISTICATED PACER. THE EQUIPMENT IS NOT AN ENTICEMENT TO THE DOCTOR, BUT A NECESSARY TOOL FOR HIM TO USE OUR PACEMAKER.

I WANT TO GO ON RECORD HERE AS I HAVE DONE IN MANY OTHER FORUMS THAT IT IS ABSOLUTELY AGAINST COMPANY POLICY TO ENGAGE IN ANY ACTIVITY THAT IS ILLEGAL, IMPROPER, OR UNETHICAL; AND IN PARTICULAR IT IS AGAINST COMPANY POLICY TO MAKE KICKBACKS, PAYOFFS, OR ANY OTHER KIND OF IMPROPER PAYMENT TO ANYONE IN THE MEDICAL INDUSTRY OR ANYWHERE ELSE.

WE JUST DON'T ENGAGE IN THOSE KIND OF ACTIVITIES.

I WOULD LIKE TO NOW MAKE A FEW GENERAL COMMENTS CONCERNING THE RECOMMENDATIONS THE STAFF HAS PROPOSED AS PART OF THEIR REPORT.

THE REPORT INDICATES THAT THE ALLEGED PROBLEMS HAVE BEEN INVESTIGATED BY THE SEC, THE FTC, THE VA, AND THE GAO. IF, IN FACT, THE PROBLEMS ARE SO ACUTE, WE HAVE SEEN NOTHING FROM THESE AGENCIES INDICATING SEVERE PROBLEMS. MOREOVER, THE STAFF HAS SUGGESTED THAT THE DHHS CONSIDER A NUMBER OF STEPS WHICH WE BELIEVE WOULD REDUCE THE EFFECTIVENESS OF THE SUPPLY OF MEDICAL SERVICES TO THE AMERICAN PUBLIC. FOR EXAMPLE, THE SUGGESTION THAT PACEMAKER IMPLANTATIONS BE CENTRALIZED IN SELECTED LARGE HOSPITALS SIMILAR TO THOSE EMPLOYED FOR CAT SCANNERS REQUIRES A GREAT DEAL MORE STUDY BEFORE ANY SUCH DRASTIC STEP BE TAKEN. THE SUGGESTION THAT EXPLANTED PACEMAKERS NOT BE RETURNED TO THE MANUFACTURER IS ABSURD. HOW ELSE CAN WE DETERMINE HOW OUR PACEMAKER WORKS, WHY A PACEMAKER APPEARED TO BE DEFECTIVE OR CEASED TO OPERATE IF WE CANNOT DISASSEMBLE IT AFTER EXPLANTING? THE SUGGESTIONS AND RECOMMENDATIONS RELATING TO THE FOOD AND DRUG ADMINISTRATION ARE SIMILARLY MISPLACED. THE AMERICAN MEDICAL DEVICE INDUSTRY IS HIGHLY REGULATED. BEFORE A NEW PRODUCT CAN BE BROUGHT TO MARKET, IT

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MUST BE EXTENSIVELY TESTED. DETAILED CLINICAL TESTING PROCEDURES ARE IN PLACE AND, AS A RESULT, AMERICA HAS THE HIGHEST QUALITY MEDICAL SERVICES AVAILABLE.

I WISH WE WERE IN A POSITION TODAY TO PROVIDE ALL OF YOU WITH A MORE DETAILED ANALYSIS OF THE MATTERS CONTAINED IN THE STAFF REPORT AND ITS CONCLUSIONS. HOWEVER, WITH HAVING RECEIVED THE REPORT LATE YESTERDAY AFTERNOON IT SIMPLY WAS NOT HUMANLY POSSIBLE TO DO SO. WITH YOUR PERMISSION, WE WILL PREPARE AND SUBMIT A FULL WRITTEN REPORT AS SOON AS POSSIBLE.

IN SUMMARY, I WOULD OFFER THAT WHEN NEWS OF THIS INVESTIGATION BECAME PUBLIC IN EARLY JULY, I WAS QUOTED IN THE NATIONAL NEWS MEDIA AS PERSONALLY WELCOMING AN INVESTIGATION IF IMPROPRIETIES EXISTED. I ALSO SAID THAT I HAD CONTACTED THE GOVERNMENT TO OFFER MY FULL AND COMPLETE COOPERATION. THAT IS WHY I AM WITH YOU TODAY.

CERTAINLY, NO SYSTEM IS PERFECT. I BELIEVE WE WOULD ALL AGREE ON THAT. AND IF THERE ARE INEQUITIES IN THE MANNER IN

WHICH THE ENTIRE PACEMAKER INDUSTRY IS CONDUCTED, THEN CHANGES SHOULD AND MUST BE MADE. AGAIN, I WOULD SUBMIT THAT THE BEST, MOST SENSIBLE WAY TO APPROACH SUCH CHANGES RESIDES IN THE COLLECTIVE EFFORTS OF THE MEDICAL COMMUNITY, THE INDUSTRY, AND THE GOVERNMENT.

FOR OUR PART, INTERMEDICS STANDS READY TO GO ABOUT THAT TASK WITH FULL AND READY COOPERATION.

I WOULD BE PLEASED TO ANSWER YOUR QUESTIONS.

Senator HEINZ. Let me ask Mr. McFarlin, on the first page of your prepared remarks, you indicated the failure of your firm to engage in improper sales practices has cost Medtronic business. To what extent has that occurred?

Mr. MCFARLIN. Well, that is a difficult question to answer specifically, in the sense that we have lost market share, probably over the last 5 years, for a number of reasons. Certainly, our refusal to engage in some of the practices going on in the industry has been one of those reasons.

Senator HEINZ. And on page 5 of your prepared statement, you indicate that you want an environment of fair and open competition. What do you think we ought to do to achieve that?

Mr. MCFARLIN. I guess I would go back to my earlier statement, that as far as the illegalities go, I think you enforce the law, and you punish the guilty. As far as the environment, certainly, some of the direction we see toward more competitive health care, we feel is constructive.

Senator HEINZ. I noted that, and I think Senator Durenberger has been a leader in that, and I welcome that further involvement of the Finance Committee Health Subcommittee.

Mr. Chambers, on page 2 of your remarks, you indicate the committee's estimate of the cost of making a pacemaker, the manufacturing cost of a pacemaker, is in error. I would tell you that that figure was provided by a former corporate officer of Intermedics. If it is inaccurate, what is the true direct cost of making your pacemaker?

Mr. CHAMBERS. I cannot comment on the former officer and whether he was. I heard other people here today who were not exactly what they said they were. But the cost of our pacemaker is roughly 25 percent of the sales price.

Senator HEINZ. May I say, that is in line with what people did say today.

Mr. CHAMBERS. Yes; it is. That is correct. Now, that is the cost of the pacemaker only. That does not include the R&D; it does not include——

Senator HEINZ. I understand that. My question was specifically phrased as direct manufacturing cost.

Mr. CHAMBERS. Yes, the estimate is about $1,000 for a $4,000 pacemaker.

Senator HEINZ. All right, fine. On page 3, you make the following statement: "In terms of educational trips and programs conducted for implanting physicians, who, if not the pacemaker manufacturers, assumes that responsibility?" That is to say, I assume, for educating physicians about pacemakers. Then you say, "Certainly not our medical schools."

I find that a somewhat extraordinary statement, if I understand you correctly. It seems to me that physicians have a professional responsibility to be educated and well-informed and that the reason we have medical schools and teaching hospitals and continuing education programs is so that their education over the years is conducted on a professional basis, as opposed to a training of whatever quality that may be conducted by an institution, a company, that is out to try and make money as a result of whatever it is they are offering.

Do you really believe that manufacturers ought to be educating the medical community about how to do everything with the patient?

Mr. CHAMBERS. I will answer your first statement. It is an extraordinary statement, but it is true. And it is true because I have studied it, I have checked on it. I have opinions from numerous doctors. And I can say that during the—let us be specific—in the last 2 years, 1981 and 1982, there have been over 500 doctors, nurses, technicians, working with the doctors, who have visited our plant for this educational purpose. Now, I have heard all of the conversation, and I did read the part of the report that says we have boats and planes and whatever, at Freeport, Tex. But in checking the records, I note that over 70 percent of the doctors and the others who visit Freeport, Tex., have nothing whatsoever to do with the boat or the planes or "goose hunting," as they sometimes refer to a "goose-hunting lodge." I have personally never been on the boats, and I have never "goose hunted." But I——

Senator HEINZ. You may be missing something.

Mr. CHAMBERS. I probably am, but I have not had that time. I might add that I am an engineer, but I am new to the pacemaker business. I have only been in it the last 3 years, and I am as mystified by some of the things as everybody else.

But my point is, that the doctors come to Freeport for training. Some of them go fishing after they come.

Senator HEINZ. Well, in fairness to you, Mr. Chambers, I do understand that in the 2 or 3 years you have been associated with this company, you have made a lot of efforts to improve its performance and to clean up what might be considered, charitably, unprofessional, less charitably, shoddy, practices, and I do understand your company has made, under your stewardship, a considerable amount of progress. Nonetheless, I assume that most of the people who do use the boat or the airplane, are in fact doctors.

Mr. CHAMBERS. Yes.

Senator HEINZ. On page 4 of your statement, you indicate that ancillary pacemaker equipment is loaned to doctors, so they can monitor and follow the patient. If indeed these are loaned, is that equipment carried on your inventory, your corporate inventory, and is it depreciated the way normal inventory would be depreciated?

Mr. CHAMBERS. Yes, it is.

Senator HEINZ. And the IRS knows this—I mean. You claim tax deductions based on depreciation of equipment?

Mr. CHAMBERS. Yes. It is carried like any other piece of capital equipment.

Senator HEINZ. I have just one last question, before I yield to Senator Durenberger.

Senator DURENBERGER. John, we have about 5 minutes left on this vote.

Senator HEINZ. All right, gentlemen, we have a vote on. We can be back here in about 7 or 8 minutes, either Senator Durenberger or myself. I am going to recess the hearing for 10 minutes. I apologize for the interruption.

The hearing is recessed.

AFTER RECESS

Senator HEINZ. The hearing will come to order.

Before I yield to Senator Durenberger, there is really just one question that comes to mind as a result of hearing the testimony from both of you, Mr. McFarlin and Mr. Chambers, and that is, both of you have in one way or another said either, "We do not do it," or "We do not countenance it," or "There are no problems here, or if they are, they are very isolated, and none of this involves corporate policy." My question to you is, if it is not Medtronic or Intermedics that is doing anything, is it true we just do not have any problems or are there real problems?

I would like to address that to you, Mr. Chambers. Do you think that everything that has been testified to by four doctors, a panel of patients, some former salesmen, plus the work over weeks and months that is on film, that has been transcribed, that has been turned over to the FBI, that has all been very carefully and, I think, properly done—is that all just one or two isolated instances, or are there some real problems in the industry and the way medicare really invites greed into the pacemaker industry?

Mr. CHAMBERS. I think that medicare does invite greed. And I heard many statements this morning that said it needs to be monitored in a little different way, it needs to be checked; additional facts need to be gathered as to what are the problems. This is a bad rumor business, and I have heard everything that has been said this morning mentioned in hundreds of different ways, and when I go check on them, I find that a lot of them are rumors. It is very difficult for me to check. I try, and I try to get people to check. I know there is something wrong. I do not exactly know where it is. Everybody says it is everybody else. And you know it is going on. But we need to make a concerted effort, both industry, doctors, and the Government, to find out what it is, and then do what we think is the right thing about it.

Senator HEINZ. The Federal Trade Commission first investigated this industry, your industry, before you were associated with it, in 1977. They claimed to have turned over their files for prosecution to the Department of Justice. Assuming that the other investigations, such as one done by congressional committees subsequent to that, were noticed by the industry, here we are, 4 or 5 years later, and it would appear that the problems, on balance, have not gotten any better, that medicare certainly is losing unnecessarily more, not less, money. Why, would you guess, if my assumptions are correct, that the industry has not cleaned up the act or has not come to Congress saying, "Listen, we think we are going to get a black eye here, unless there are some controls put in the industry"?

My great-grandfather happened to be in the food business. He started a small company, located in Pittsburgh, and he was very concerned that there were shoddy practices in the food industry, and he lobbied Congress personally very hard, a little after the turn of the century, to create, to pass the pure food and drug laws and to, in effect, create what has now become known as the FDA. Now, maybe we had a more enterprising spirit in those days, and people did not check with their lawyers or whatever before they came down here and urged reform for reform's sake. But I am unaware of the industry at any point, up until maybe today, coming before us and urging reform. Where has the industry been?

Mr. CHAMBERS. I do not think the industry is as bad as it is made out to be. Now, when you talk about the industry, I am confining my statements to the manufacturing portion of it, and as I notice, your own number says that in 1982, I believe the cost of medicare is $2.25 billion, and there is about $500 million of that that is the manufacturing cost, and that is roughly 25 percent of the problem.

Now, we have done a lot of things that have not been mentioned here, and they did not quite get around to on "20/20" last night, but for example, if you were to take a pacemaker that was manufactured in 1965, and the cost was about $750, and you would compare it to 1982, the cost of that same pacemaker, and took 10-percent inflation a year, you would find only about $100 difference between the present pacemaker and that pacemaker in 1965. Now, if you would divide the difference in years, the 17 years, by the life of the pacemaker at that time, you would find that it would have taken about eight operations, costing $1,000 or $1,500 each, and all of the hospital fees, so you will find that the price of the pacemaker for the same pacemaker has gone down.

We have also prepared all of the other advantages of a pacemaker that have been mentioned here this morning, so that for a slight difference between $3,300 and $4,000, we are getting a lot different type of pacemaker. Now, I heard the young lady, Mrs. Garman, this morning. She was talking about her implant, and I believe that she said her original pacemaker was an Intermedics pacemaker. Now, that is not true. Her original pacemaker was an Amtak pacemaker, which is a California company. And because—and I contradict the statement that all pacemakers are alike—that happened to be a pacemaker made by a fairly new company, and that new company had failures because of either quality control or, as I was told, a capacitor failure, and there was a recall, and the company went bankrupt, and they did not honor their warranty.

Now, Intermedics did not have to honor that warranty, but when they came to us and asked for another pacemaker, we were not obligated to do anything but sell the pacemaker to them, but we gave this lady $450, because we felt sorry; it was not her fault that she had had implanted a pacemaker that was no longer available. We gave her the $450.

We give pacemakers to indigent patients, in lots of cases, and we give pacemakers to people who cannot pay. And we have reduced the cost of some of our pacemakers. We have not always increased them. And we give a lot more for the money now than when we started manufacturing them in 1975. And I can go on and on and on about things that we have done that have never been mentioned.

I will give you one final thing. For example, Intermedics monitors each pacemaker of ours that is implanted, and I figured the cost of that last night. It represents $3 million a year, roughly, that medicare is willing to pay. We do not bill medicare for that. Other companies do, but Intermedics does not. We give that freely for two or three reasons. One, is because we get more information about our pacemakers, and it helps us to build a better pacemaker, and we think that we do many things for reasons other than the financial reward for it.

Senator HEINZ. I am interested—you mentioned that monitoring. I understand that you are not the company that does monitor for physicians their pacemaker patients. But the question I asked earlier was, do you care about the extent to which doctors are billing medicare $25 for each piece of paper you send out? How many pieces of paper do you send out each day, each week, each month? How many pacemakers do you monitor, and how often do you monitor them?

Mr. CHAMBERS. We monitor between 5,000 and 10,000, and I do not have any idea how many pieces of paper we send out.

Senator HEINZ. Well, how frequently do you monitor?

Mr. CHAMBERS. I am guessing. I would say at least once a month, certainly for the early implants.

Senator HEINZ. So, if you take the high figure, that is 120,000 monitoring operations a year, at $25 each, that comes out a pretty healthy number of, let us say, $3 or $4 million; is that right?

Mr. CHAMBERS. That is right.

Senator HEINZ. And you do not charge that to the doctors?

Mr. CHAMBERS. No.

Senator HEINZ. But maybe the doctors charge it to medicare.

Mr. CHAMBERS. They might. If they do, they should not.

Senator HEINZ. There is nothing illegal about it?

Mr. CHAMBERS. I do not know whether there is or not. I would think that, listening to some of the testimony this morning, they could argue that they did things other than just look at it. Now, we are supplying the information, and what they do to it from that point on, I do not know. I would imagine that there are those that charge and those that do not charge for it.

Senator HEINZ. Mr. McFarlin, before I yield to Senator Durenberger, do you have any comments?

Mr. MCFARLIN. In terms of the monitoring?

Senator HEINZ. No. I had asked a more general question, which is, if nobody is doing anything wrong, why are we having this hearing?

Mr. MCFARLIN. Well, in response to some of the comments made, I think the medicare system does not necessarily invite illegal behavior. A lot of companies participate in this marketplace, and the same medicare system serves all companies, but not all companies are involved in illegal activities. So I guess the only input I could give there is that closer monitoring, I think, would be useful in the system, to prevent the abuses that do go on.

Senator HEINZ. Thank you.

Senator Durenberger?

Senator DURENBERGER. Thank you, Mr. Chairman.

Mr. McFarlin, based on the staff report and the statements that we have heard today, one might be led to believe that pacemakers are all pretty much the same. What is your view on that? Are there significant differences?

Mr. MCFARLIN. Well, I think pacemakers differ in a variety of ways, and that has been one of the concerns for us, of the things that we have heard here. Pacemakers are not generic any more than patients are generic. There are many forms of heart disease. There are many different types and models of pacemakers to specifically treat certain types of diseases. So from a pacing modality standpoint, there are certainly differences, and then if you look at individual pacemakers from individual manufacturers, if you look at all of the manufacturers in the United States, or in the world, however you choose to do it, there are significant differences in quality and reliability and features, and a number of other things. Pacemakers are definitely not generic.

Senator DURENBERGER. What is Medtronic's experience with replacements, and what are some of the major reasons for replacement?

Mr. MCFARLIN. Do you mean warranty replacements?

Senator DURENBERGER. Well, any kind of replacement, including a warranty replacement.

Mr. MCFARLIN. Oh, in terms of replacements, I assume you refer to some of the numbers that have been referred to here——

Senator DURENBERGER. Yes. I have not been able to keep track of all of the numbers here, so——

Mr. MCFARLIN. I think one number used was 30 percent replacements, or 30 percent of the business was replacement business. All I can say is, that would be nice. Our number is about 12 percent. So I am not sure what the source of that 30 percent number is.

Senator DURENBERGER. What is the reason for replacement, other than warranty? Is there any?

Mr. MCFARLIN. Well, of course, pacemakers have a battery in them, and over a given number of years, that battery depletes. That is the bulk of replacements. From time to time, there are failures, and those constitute replacements, too.

Senator DURENBERGER. Is there any evidence in the industry of replacements being made through the process of competing for product between companies?

Mr. MCFARLIN. Replacements being made through the process of competing for product?

Senator DURENBERGER. Yes. In other words, we have heard a lot about sales kickbacks and a variety of other marketing schemes here today, and the thought just occurred to me as I was listening to that that if the alleged relationships that exist between some sales personnel and some physicians is accurate, that perhaps some replacements might be taking place not because of a failure of the pacemaker or of the battery.

Senator HEINZ. Could you withhold for a minute? Excuse me. [Conferring with Senator Durenberger.]

Senator DURENBERGER [presiding]. Thank you. Was there an answer?

Mr. MCFARLIN. Yes. I was going to say that it would really be a matter of medical judgment as to when and why a replacement occurs, and it would only be conjecture on my part to say anything beyond that.

Senator DURENBERGER. Let me ask you the question I asked somebody else earlier on this morning about costs. We have been throwing this cost figure around here as though this were the glue industry, which I used to come from, or some other industry. And I am concerned for what H. J. Heinz may have done for the cost of pacemakers by getting the FDA started. [Laughter.]

I wonder if, generally, you would go through for us, either using your own company as an example, or the industry, whichever you choose, in terms of the overall costs, the manufacturing costs, the quality control, the regulatory costs, the selling expenses, and so forth?

Mr. MCFARLIN. Well, I can only speak for Medtronic; I cannot speak for the industry. But in terms of our cost structure, the numbers used in the range of $600, $800, and $1,000, are basically correct. That is a basic number for what we refer to as "labor, burden, and material" in the building of the device—the labor to assemble it, the overhead on that labor, and the actual piece parts that go into it. That constitutes—at least at Medtronic, if you take our product line in aggregate—about 35 percent of our revenues. If you add on top of that research and development at about 8 to 10 percent, and then add our selling, general, and administrative expenses at about 38 percent; and I am a little surprised by some of the selling expense numbers I hear in the report. We could not afford those kinds of numbers. Our selling expenses in the United States are only 16 percent of sales. But if you add that up, that should be roughly about 80 percent of the sales price of the pacemaker, which leaves a profit before taxes of about 20 percent, and an after-tax profit of about 13 or 14 percent. So that is basically our cost structure.

Senator DURENBERGER. Where is the whole area of regulatory compliance and the FDA requirements, and so forth?

Mr. MCFARLIN. That is in our general and administrative expense, and since the 1976 medical device amendments, and then the more recent advent of the premarket approval process, our cost to place a product on the marketplace has increased substantially. As a matter of fact, in Medtronic, we are a company of about 4,800 people, and one person out of six in Medtronic is involved with quality, reliability, and regulatory compliance. So that is the magnitude of what we do as a company, both for the quality and reli-

ability of our products and to comply with the requirements of the FDA.

Senator DURENBERGER. Let me explore with you, then, the issue of selling expense. We heard testimony from some former salesmen to the effect that, as I recall, the cost for an employed salesman would run in the neighborhood of $30,000, plus a car, fringe benefits, and so forth, whereas the independent salesmen, or whatever we are referring to them as, can make as much as $30,000 a month. And if they do not make $100,000 a year, they are no good, and they get thrown out of the company. Would you describe for me generally how marketing practices of that nature differ within the industry?

Mr. MCFARLIN. Well, again, representing Medtronic only, our commission structure is 3 percent of sales. I have heard some numbers of 30 percent or 50 percent, but our figure is 3 percent of sales. That is on a base of—we pay a base salary to a salesperson of about—I would say it would average about $30,000 a year—and then a commission on top of that of 3 percent of sales.

Senator DURENBERGER. What other practices that you are aware of that go on in the industry?

Mr. MCFARLIN. Well, for companies with nondirect sales forces through distributors and so forth, there is a whole spectrum of compensation means.

Senator DURENBERGER. Can you describe some of that for us?

Mr. MCFARLIN. Well, distributorships are independent businesses unto themselves, and many of them are incorporated, many of them are partnerships. They are run as a distribution company, and there is a whole spectrum of distribution companies, some of which are very conservative, some of which are very liberal. I have heard of per pacemaker commissions—and I cannot verify, this is hearsay—of $1,200 per pacemaker, or $1,250 per pacemaker. In contrast, one of our salesmen makes $120 to sell a pacemaker.

Senator DURENBERGER. Has your company ever had occasion to file a formal complaint with any Federal agency over industry practices and marketing, or to initiate any suits within the industry over marketing practices?

Mr. MCFARLIN. We have been aware of improper marketing practices in this industry for some time—and that is not to imply that it has been static. Marketing practices in this industry have changed dramatically in the last 5 or 6 years. Previously, the bulk of companies were direct, although not all, but in the last 5 or 6 years, practices have changed dramatically. We have been aware that investigations were underway. I guess there are probably two or three parallel investigations going on, some of them stretching back beyond 2 years ago, and we have cooperated with those investigations as appropriate and as asked to.

Senator DURENBERGER. Have you initiated any lawsuits over marketing practices against anybody else in the industry?

Mr. MCFARLIN. Yes, we have.

Senator DURENBERGER. I have no further questions. I thank you both for being willing to participate in this. It is obviously not easy after you see the title of the program today, "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry," and we appreciate

your contributions to our understanding of the problem. Thank you.

The hearing is adjourned.

[Whereupon, at 1:50 p.m., the committee was adjourned.]

APPENDIXES

Appendix 1

BILLS OF PACEMAKER RECIPIENTS

ITEM 1. INITIAL BILL OF MADELINE GARMAN

[redacted]

STATEMENT 1st Transplant

C. A. LUER, M.D. 58058 — J. O. FERGESON, M.D. 58074
W. L. CHAPMAN, M.D. 58136 — J. W. REEDER, M.D. 58186 — F. H. PFEIFFENBERGER, M.D. 58142
PROFESSIONAL ASSOCIATION
GENERAL, THORACIC AND CARDIOVASCULAR SURGERY
SUITE 222 • 1950 ARLINGTON STREET
R. W. HOEFER, M.D., 58240 — SARASOTA, FLORIDA 33579 — TELEPHONE: 366-4282
Surgeon

Madeline Garman
926 Whitfield Av
Sarasota, Fla. 33580

☐ OFFICE ☐ HOSPITAL Memorial MEDICARE NO.

FOR PROFESSIONAL SERVICES Dr Hoefer

DIAGNOSIS: Intermittent heart block

PROCEDURE: DATE 1-5-79 Insertion of cardiac pacemaker
33205 $885.00

PAID
JAN 30 1979

ADM 12-26-78 DISCH 1-10-79

SURGICAL ASSIST TO DR.

TAX ID #59-1300601
NO DUPLICATE BILLS WILL BE ISSUED
PLEASE RETAIN ONE COPY FOR YOUR FILE

TOTAL $885.00

~~Copied from Card~~
Copy - Model # DU-15 } I carry cards
Serial # B-1402 }

BEST COPY AVAILABLE

STATEMENT

GULF COAST ANESTHESIOLOGY ASSOCIATES

1837 HILLVIEW STREET
SARASOTA, FLORIDA 33579
PHONE 366-5515

Madeline M. Garman
926 Whitfield Ave.
Sarasota, Fla. 33580

Edward A. Ellis, M.D.

NUMBER	DATE	DESCRIPTION	CHARGE	PAYMENT	CURRENT BALANCE
7583	1/5/79	Anesthesia	165.00		165.00
Local anesthesia with IV supplementation for: #33205-30 Time: 6:55-8:00 Memorial Hospital					

1-30-79
GULF COAST ANESTHESIOLOGY ASSOCIATES

16767

PLEASE PAY LAST AMOUNT IN THIS COLUMN

59-1353626

THIS IS A COPY OF YOUR ACCOUNT AS IT APPEARS ON YOUR LEDGER CARD

BEST COPY AVAILABLE

STATEMENT

Eugene D. Liddy, M.D.

INTERNAL MEDICINE & CARDIOLOGY

MEDICAL ARTS BLDG. — 1950 ARLINGTON STREET

SARASOTA, FLORIDA 33579

Mrs. Madeline Garman

926 Whitfield Avenue

Sarasota, Florida 33580

DATE	DESCRIPTION	CHARGES	CREDITS	BALANCE
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
12/26/78 thru				
12/31/78	Hospital visits	$210.00		
1/3/79 thru				
1/9/79	Hospital visits	$175.00		$395.00

12/26/78 90220 $85.00, 12/27 thru 12/31/78 daily 93277 @ $25.00 per day. 1/3/79 thru 1/9/79 daily 93277 @ $25.00 per day.

Cardiac arrhythmia variable in type. Periods of advanced auriculoventricular block, congestive heart failure.

PAID 1-22-79

PLEASE PAY LAST AMOUNT IN THIS COLUMN

Hospital stay

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STATEMENT

Eugene D. Liddy, M.D.
INTERNAL MEDICINE & CARDIOLOGY
MEDICAL ARTS BLDG. — 1950 ARLINGTON STREET
SARASOTA, FLORIDA 33579

Mrs. Madeline Garman
926 Whitfield Avenue
Sarasota, Florida 33580

DATE	DESCRIPTION	CHARGES	CREDITS	BALANCE
4/22/78	Paid		$33.00	00.00
5/30	90060	$20.00	$20.00	
6/29	90060	$20.00		$20.00
7/8	Paid		$20.00	00.00
9/28 thru				
10/9	Hospital visits	$216.00		$216.0
10/27	Paid		$216.00	00.00
12/26/78 thru				
12/31/78	Hospital visits	$210.00		
1/3/79 thru				
1/9/79	Hospital visits	$175.00		$385.0
1/22/79	Paid		$385.00	00.00
3/26	90060	$20.00	$20.00	
8/6	90060	$25.00	$25.00	
8/27	90060	$25.00		
	Flu vacc.	$10.00		$35.00

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NOTICE: ANYONE WHO MISREPRESENTS OR FALSIFIES ESSENTIAL INFORMATION REQUESTED BY THIS FORM MAY UPON CONVICTION BE SUBJECT TO FINE AND IMPRISONMENT UNDER FEDERAL AND OR STATE LAW

MEMORIAL HOSPITAL
1901 ARLINGTON ST.
SARASOTA FL 33579

A NOT FOR PROFIT HOSPITAL OWNED AND OPERATED BY THE SARASOTA COUNTY PUBLIC HOSPITAL BOARD

(2) HOSPITAL NO	(3) PROVIDER NO	(4) FED. I.D. NO	(5)
10176-1	513	100087	59-60-12500

(6) PATIENT'S LAST NAME	FIRST NAME	INITIAL	(7) STREET ADDRESS	CITY	STATE	ZIP
GARMA-	M CADELINE		926 WHITFI LD AVE	SAR.SOTA	FL	33580

(8) PATIENT CONTROL NO	(9) SEX	(10) BIRTHDATE	(11) ATTENDING PHYSICIAN	(12) ADMISSION-START OF CARE DATE	HR	(13) QUALIFYING STAY DATES FROM	THRU	(14) M N PLAN EST
12133 7 A1	2	03	LIDDY	12 07	11			

(15) PRIMARY PAYOR NAME	(16) INSURED'S NAME & RELATIONSHIP TO PATIENT	(17) CLAIM CERTIFICATE I.D. NO (H I C)	(18) GROUP NAME NO	(19) Y N
MEDICARE		262488722D		Y
(20) SECONDARY PAYOR NAME	(21) INSURED'S NAME & RELATIONSHIP TO PATIENT	(22) CLAIM CERTIFICATE I.D. NO (H I C)	(23) GROUP NAME NO	(24) Y N
BLUE CROSS	PATIENT	262488.70	CCC= 40	Y
(25) TERTIARY PAYOR NAME	(26) INSURED'S NAME & RELATIONSHIP TO PATIENT	(27) CLAIM CERTIFICATE I.D. NO (H I C)	(28) GROUP NAME NO	(29) Y N

(30) BILL TO
- MADELINE GARMAN
- 26 WHITFIELD AVE
- SARASOTA FL 33580

(31)

(32) TYPE OF BILL: 12

PROFESSIONAL COMPONENTS (33) RADIOLOGY (34) PATHOLOGY (35) OTHER

(36) MOST COMMON R.M-PVT RATE: 09400 (37)

(38) REVENUE CODE	(39) DESCRIPTION	(40)	(41) TOTAL CHARGES	(42) PRIMARY PAYOR	(43) SEC. PAYOR ITEM 29	(44) TERT PAYOR ITEM 29	(45) PATIENT
51	SEMI-PRIVATE 104.00	013	156000	156000			
02	OPERATING ROOM		23100	23100			
05	ANESTHESIA SUPPLIES		1200	1200			
06	LAB		19550	19550			
08	X-RAY		6300	6300			
10	DRUGS-SOLUTIONS		23035	23035			
11	STERILE SUPPLIES		27325	27325			
96	CARDIAC PACEMAKER IMPLANT		23000	23000			
16	[illegible]		15000	15000			
27	NUCLEAR MEDICINE		2250	2250			
	TOTALS →		342685	342685			

(46) BLOOD RECORD (PINTS) PURN	REPLACED	NOT REPLACED	(48) CHG/PT	(47) BLOOD DED	(49) TREATMENT AUTHORIZATION	(50) INPATIENT DEDUCTIBLE	(51) DEDUCTIBLES	(52) DEDUCTIBLES	(53) DEDUCTIBLES	(54) PAID BY PATIENT
							14400			

(55) STATEMENT COVERS PERIOD FROM	THRU	(56) PS CODE	(57) (58) HMO	COINSURANCE DAYS	(59) RATE	(59) L.R. DAYS USED	(71) PRF	(72) E.R.	(73)	(74) COINSURANCE	(75) COINSURANCE	(76) COINSURANCE	AMOUNT DUE ▼
12 07	01 11 79	DA	08			1							

(77) OCCURR DATE	(78) CODE	(78) OCCURR DATE	(80) CODE	(81) COV DAYS	(82) % COINS DAYS	(84) DUE FROM PRIMARY PAYOR	(85) DUE FROM SEC. PAYOR ITEM 29	(86) DUE FROM TERT PAYOR ITEM 29	(87) DUE FROM PATIENT
						328285	14400		

NOTICE TO PATIENT: THE HOSPITAL IS ACTING SOLELY AS AN AGENT FOR THE PATIENT IN FILING FOR ASSIGNED INSURANCE BENEFITS AND THEREFORE IT CAN ASSUME NO RESPONSIBILITY FOR THE GUARANTEE OF COVERED CHARGES AS SHOWN FOR PRIMARY AND SECONDARY PAYORS. ACTUAL CREDIT WILL BE GIVEN WHEN THE MONEY IS RECEIVED.

SHOULD AN OVERPAYMENT BE MADE, A REFUND CHECK WILL BE SENT TO THE AUTHORIZED PARTY.

UB16-78

REFER QUESTIONS TO YOUR PATIENT REPRESENTATIVE
PATIENT COPY

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FORM SSA-1533 (1-77)

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE / SOCIAL SECURITY ADMINISTRATION

MEDICARE HOSPITAL, EXTENDED CARE AND HOME HEALTH BENEFITS RECORD

J154903190394552 100087

DATE: 02/16/79

MADELINE GARMAN
926 WHITFIELD AVE
SARASOTA FL 33580

HEALTH INSURANCE CLAIM NUMBER

262-48-8722D

Always use this number when writing about your claim.

THIS IS NOT A BILL. This notice is to give you a record of the Medicare benefits you used during the period shown in Item 1. For important additional information please see the other side of this form.

1 OUR RECORDS SHOW THAT YOU RECEIVED THESE SERVICES

Type of Services	Services Were Provided By	Date
INPATIENT HOSPITAL	MEMORIAL HOSP 1901 ARLINGTON ST SARASOTA FL 33579	12/26/78 THRU 01/10/79

2 MEDICARE HAS PAID FOR ALL COVERED SERVICES EXCEPT

$144.00 FOR THE INPATIENT DEDUCTIBLE.

IF YOU HAVE ANY QUESTIONS ABOUT THIS RECORD PLEASE GET IN TOUCH WITH:

BLUE CROSS OF FLORIDA INC
PO BOX 2711
JACKSONVILLE FLORIDA 32201

3 OUR RECORDS SHOW THE FOLLOWING BENEFITS WERE USED THIS TIME

Inpatient Hospital Days	Lifetime Reserve Days	Extended Care Days	Home Health Visits Hospital Insurance	Home Health Visits Medical Insurance
15				

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Blue Cross

P.O. Box 1798
532 Riverside Avenue
Jacksonville, Florida 32231
(904) 354-3331

Contract Number	Patient Name	Date Claim Paid	Batch Number
262488670	GARMAN M	02-03-79	
Group Number	**Division Number**	**Hospital Code**	**Type Service**
99999	SEA	513	1
Admission Date	**Death Date**	**Hospital Name**	**Days Approved**
12-26-78		MEMORIAL HOSPITAL	

GARMAN MADELINE M
926 WHITFIELD AVE
SARASOTA FLA
33

The statement represents a summary of how your recent hospital charges were processed. On the reverse side you will find an explanation of codes used on this statement.

Days Paid	Claim Number	
000		
Amt. Paid	**Payment Appr. No.**	**Date Claim Received**	**Amt. Charged**	**Deductible**
144.00	1313397	01-31-79	144	0
			Disposition	
			PD TO HOSPITAL	

DESCRIPTION	CHARGES	PAYMENT
MEDICARE DEDUCTIBLE	144.00	144.00
TOTAL	144.00	144.00

THIS IS NOT A BILL
PLEASE RETAIN THIS COPY FOR YOUR FILES
DUPLICATES CANNOT BE PROVIDED
11-485 007

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ITEM 2. REPLACEMENT BILL OF MADELINE GARMAN

RICHARD W. HOEFER, M.D., P.A., F.A.C.S.
General, Thoracic and Cardiovascular Surgery
DOCTORS HOSPITAL MEDICAL COMPLEX, SUITE 303
2650 BAHIA VISTA STREET
SARASOTA, FLORIDA 33579
(813) 957-1168

2nd.

Mrs. Madeline Garman
926 Whitfield Ave.
Sarasota, Fl. 33580

355-3235

NUMBER	DATE	DESCRIPTION	CHARGES	PAYMENT	CURRENT BALANCE
5193	3/2/81	Surgical Consultation req by Dr. Liddy	60 -	-0-	60 -
	3/13/81	Hospital Admission	n/c	- -	60 -
0217	3/14/81	Pacemaker Battery Replacement	150	- -	510
	3/13/81	Hospital Discharge			

3d ck 786 6-11 81

Copied from new card I carry -
Model. #253-04
Serial # 12955

PLEASE PAY LAST AMOUNT IN THIS COLUMN

THIS IS A COPY OF YOUR ACCOUNT AS IT APPEARS ON YOUR LEDGER CARD

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Dx; Arteriosclerotic heart disease, cardiac decom
STATEMENT
pensation,
Osteoporosis & osteoarthritis of the spine,
cardiac arrhythmia
Eugene D. Liddy, M.D. diabetes mell
essential
INTERNAL MEDICINE & CARDIOLOGY
hyper
MEDICAL ARTS BLDG. — 1950 ARLINGTON STREET
tension
SARASOTA, FLORIDA 33579

Mrs. Madeline Garman

926 Whitfield Avenue

Sarasota, Florida 33580

DATE	DESCRIPTION	CHARGES	CREDITS	BALANCE
5/13/80	90060 office visi	$25.00	$25.00	
9/22	90060 office visit	$25.00	$25.00	
9/30	90070 ofc. v.pelis	$30.00		
	81000 urine	$ 5.00	$35.00	
4/2/81	90060 office visi	$30.00	$30.00	00.00
5/13/81	Sarasota Memorial Hospital			
	90602 Consultation by requested			
	DR. R. Hoefer	$40.00		
5/14/81	90260 hospital Visi	$30.00		$70.00
	Diagnosis:			
	Defective pacemaker,			
	admitted for replacement of the			
	pulse gemerator.			

PLEASE
PAY LAST AMOUNT
IN THIS COLUMN

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DX: A.S.H.D., CARDIAC DECOMP., CARDIAC ARRHYTHMIA ESSENTIAL HYPERTENSION, OSTEOPOROSIS & OSTEOARTHRITIS OF SPINE, DIABETES MELLITUS.

STATEMENT

Eugene D. Liddy, M.D.

INTERNAL MEDICINE & CARDIOLOGY

MEDICAL ARTS BLDG. — 1950 ARLINGTON STREET

SARASOTA, FLORIDA 33579

8/31/81

Mrs. Madeline Garman

926 Whitfield Avenue

Sarasota, Florida 33580

DATE	DESCRIPTION	CHARGES	CREDITS	BALANCE
8/15/81 thru				
8/18/81	Hospital visits	$185.00		$185.00
8/15/81 90220 Initial hosp. care $90.00, 8/16 thru 8/17 daily follow up hosp. visits X 2 @ $30.00 per day, 8/18 90275 final hosp. visit & discharge summary $35.00				
Admitted for covert cardiac decomp., hypokalemia.				

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MEMORIAL HOSPITAL
1901 ARLINGTON ST
SARASOTA, FL. 33579
A NOT FOR PROFIT HOSPITAL, OWNED AND OPERATED BY THE SARASOTA COUNTY PUBLIC HOSPITAL BOARD

(2) HOSPITAL NO.	(3) PROVIDER NO.	(4) FED. I.D. NO.
10176-1	513	100087	59-60-12600

PATIENT'S LAST NAME: GARMAN,M MADELINE
FIRST NAME / INITIAL / (7) STREET ADDRESS: 926 WHITFIELD AVE
CITY: SARASOTA
STATE: FL
ZIP: 33580

(8) PATIENT CONTROL NO.	(9) BIRTHDATE	(10) ATTENDING PHYSICIAN	(12) ADMISSION START OF CARE DATE	HR	(13) QUALIFYING STAY DATES FROM	THRU	(14) H.M. PLAN SET
1-4027456 X1 2	031493	HOEFER R W	051381	14			

(15) PRIMARY PAYOR NAME	(16) INSURED'S NAME & RELATIONSHIP TO PATIENT	(17) CLAIM CERTIFICATE I.D. NO. (H I C)	(18) GROUP NAME NO.
MEDICARE	GARMAN,MADELINE SA	262 48 8722D	
(20) SECONDARY PAYOR NAME	(21) INSURED'S NAME & RELATIONSHIP TO PATIENT	(22) CLAIM CERTIFICATE I.D. NO. (H I C)	(23) GROUP NAME NO.
BLUE CROSS 090	GARMAN,MADELINE SA	262 48 8670	
(25) TERTIARY PAYOR NAME	(26) INSURED'S NAME & RELATIONSHIP TO PATIENT	(27) CLAIM CERTIFICATE I.D. NO. (H I C)	(28) GROUP NAME NO.

(29) BILL TO
- M MADELINE GARMAN 4027456
- 926 WHITFIELD AVE
-
- SARASOTA FL 33580

(30) TYPE OF BILL: 1P

PROFESSIONAL COMPONENTS (32) RADIOLOGY (34) PATHOLOGY (36) OTHER

(39) MOST COMMON SEMI-PVT RATE: 12400

(38) REVENUE CODE	(39) DESCRIPTION	(40) HCPCS	(41) TOTAL CHARGES	(42) PRIMARY PAYOR	(43) SEC. PAYOR (ITEM 29)	(44) TERT. PAYOR (ITEM 29)	(45) PATIENT
02	OPERATING ROOM		31625	31625			
05	ANESTHESIA SUPPLIES		1500	1500			
06	LABORATORY		7865	7865			
08	X-RAY: DIAGNOSTIC		2200	2200			
10	DRUGS		3736	3736			
13	SUPPLIES AND EQUIPMENT		1325	1325			
16	ELECTROCARDIOGRAM, EKG		2000	2000			
56	PACEMAKER		390500	390500			
P1	PRIVATE ROOM		28400	24800			3600

MEMORIAL HOSPITAL, SARASOTA FLA. ITEMIZED LIST OF CHARGES
A NOT FOR PROFIT HOSPITAL
LICENSED BY THE STATE OF FLORIDA 05/22/81

PATIENT: 0027856 GARCIA,M MADELINE ADMITTED 05/13/81 DISCHARGED 05/15/8

QTY	DEPT	DESCRIPTION	TOTAL	CHG CODE	TRAN #
01	LAB	SMA 6			0001
01	LAB	SMA-12			0002
01	LAB	RADIO PLASMA REAGIN (RPR) RPR			0003
01	LAB	PARTIAL THROMBO			0004
01	LAB	PROTH TIME			0005
01	LAB	CBC			0006
01	LAB	UMINALYSIS COMPLETE			0007
01	LAB	ELECTROCARDIOGRAM			0008
01	ROOM	PRIVATE ROOM			0009
01	RAD	CHEST P A & LAT-INPATIENT		6TA-675 A	0010
01	OR	SURGERY			0011
01	OR	ANESTHESIA LOCAL			0012
01	OR	PACEMAKER INTERMEDIC-CYBERLITH			0013
01	CSS	SS DEXTROSE IN WATER, 1000CC			0014
01	CSS	BLOOD SET			0015
02	CSS	SHAVE PREP PACK			0016
01	LAB	ELECTROCARDIOGRAM			0017
01	CSS	ANGIOCATH IV PLACEMENT UNIT		6TA-675 A	0018
04	PHM	PROPRANOLOL 40MG			0019
01	PHM	DRUGS			0020
01	PHM	OS-CAL TAB			0021
01	PHM	ASCORBIC ACID 500 MG TABR 0.40			0022
04	PHM	CEPHALEXIN CAPS 500MG A			0023
01	PHM	MAALOX 180ML BOTTLE			0024
01	PHM	FLURAZEPAM CAPS 15MG ORAL			0025
01	PHM	CEPHAPIRIN 2GM IVPB IN 50ML DS			0026
01	PHM	DEXTROSE 5% INJ 100CC UNDERFIL			0027
01	PHM	PROMETHAZINE 25MG IMI INJ AMP			0028
01	PHM	MEPERIDINE INJ 25MG IMI			0029
					0030

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MEMORIAL HOSPITAL, SARASOTA FLA. ITEMIZED LIST OF CHARGES
A NOT FOR PROFIT HOSPITAL 09/09/81
LICENSED BY THE STATE OF FLORIDA

PATIENT: 4207750 GARMAN,M MADELINE ADMITTED 08/15/81 DISCHARGED 08/19/81

QTY	DEPT	DESCRIPTION	TOTAL	CHG CODE	TRAN #
01	LAB	ELECTROCARDIOGRAM			0001
01	LAB	URINALYSIS COMPLETE			0002
01	LAB	SMA 6			0003
01	LAB	COMPLETE BLOOD COUNT			0004
01	ROOM	PRIVATE ROOM			0004
01	RAD	CHEST P A & LAT-INPATIENT		2NE-255 A	0005
01	LAB	ANTI-NUCLEAR ANTIBODY			0006
01	LAB	DIGOXIN			0007
01	LAB	SMA 6			0008
01	LAB	SMA-12			0009
01	ROOM	PRIVATE ROOM			0010
01	LAB	ELECTROCARDIOGRAM		2NE-255 A	0011
01	ROOM	PRIVATE ROOM			0012
01	LAB	SMA 6		2NE-255 A	0013
01	ROOM	PRIVATE ROOM			0014
06	PHM	PROPRANOLOL 40MG		2NE-255 A	0015
15	PHM	OS-CAL TABS			0016
04	PHM	ASCORBIC ACID 500 MG TAMR 0.80			0017
04	PHM	DIGOXIN 0.125MG TABS			0018
14	PHM	PROPRANOLOL TABS 10MG			0019
08	PHM	POTASSIUM CHLORIDE 10MEQ TAB			0020
01	PHM	DRUGS			0021
01	PHM	MAALOX 180ML BOTTLE			0022

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Form HCFA-1533 (8-80) (Formerly SSA-1533)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES/HEALTH CARE FINANCING ADMINISTRATION

MEDICARE HOSPITAL, EXTENDED CARE AND HOME HEALTH BENEFITS RECORD

100087

DATE: 06/19/81

MADELINE GARMAN
926 WHITFIELD AVE
SARASOTA FL 33580

HEALTH INSURANCE CLAIM NUMBER
262-48-8722D

Always use this number when writing about your claim.

No action is required of you upon receipt of this notice. This notice is to give you a record of the Medicare benefits you used during the period shown in Item 1. For important additional information please see the other side of this form.

1 OUR RECORDS SHOW THAT YOU RECEIVED THESE SERVICES

Type of Services	Services Were Provided By	Date
INPATIENT HOSPITAL	MEMORIAL HOSP 1901 ARLINGTON ST SARASOTA FL 33579	05/13/81 THRU 05/15/81

2 MEDICARE HAS PAID FOR ALL COVERED SERVICES EXCEPT

$204.00 FOR THE INPATIENT DEDUCTIBLE.

IF YOU HAVE ANY QUESTIONS ABOUT THIS RECORD PLEASE GET IN TOUCH WITH:

BLUE CROSS & BLUE SHIELD OF FLORIDA
PO BOX 2711
JACKSONVILLE FL 32203
TELEPHONE NUMBER: 1-904-791-6260

3 OUR RECORDS SHOW THE FOLLOWING BENEFITS WERE USED THIS TIME

Inpatient Hospital Days	Lifetime Reserve Days	Extended Care Days	Home Health Visits Hospital Insurance	Home Health Visits Medical Insurance
2				

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ITEM 3. INITIAL BILL OF WILLIE A. MEADOWS

MEADOWS WILLIE A
7735 AMARILLO ST
HOUSTON ,TEXAS 77020

DATE 02-25-77
PAGE 01

PAT NO 002173867
PAT TYPE 52

EASTWAY GENERAL HOSPITAL

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 02-09-77 TIME 07:00 A.M. [X] P.M. [ ]
D/R OR BAL 73.00

PATIENT AGE: 68
POLICY / GROUP NO.
DISCHARGE DATE 02-21-77 TIME 10:35 A.M. [X] P.M. [ ]
DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME

SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 09 77	MISC CENTRAL SUPPLY CHG		001	3.25		
02 09 77	EMERGENCY ROOM 1-30 MIN	B000380	001	20.50		
02 09 77	XRY CHEST 2-VIEWS	E1D1500	001	24.50		
02 09 77	ELECTROCARDIOGRAM --EKG	9063000	001	27.00		
02 09 77	DEX 5% IN D/W 1000	F526180	001	9.50		
02 09 77	MEDICUT CANNULA NOT PLS ANESTH	HG52700	001	3.50		
02 09 77	ATROPINE 0.5MG/5CC BRISTO	F	001	4.75		
02 09 77	REPLACEMENT CANNULA	J401413	001	4.00		
02 09 77	EMER. CARE MOBILE UNIT	HD21500	001	37.00		
02 09 77	INTENSIVE CARE UNIT	A201500	001	175.50		
02 10 77	INTENSIVE CARE UNIT	A201500	001	175.50		
02 11 77	ELECTROCARDIOGRAM --EKG	9063000	001	27.00		
02 11 77	OXY 02 INCL EQ EX TNT P/H	J200990	008	24.00		
02 11 77	RPR CARD RAPID PROTEIN REAGENT	6513900	001	7.00		
02 11 77	SERUM MAGNESIUM	6388650	001	4.00		
02 11 77	SERUM OSMOLALITY	6419650	001	10.00		
02 11 77	CPK ISO ENZYMES	6181475	001	20.50		
02 11 77	LDH ISO ENZYMES	6362050	001	22.50		
02 11 77	TRANSAMINASE SGOT	6625250	001	11.00		
02 11 77	LATIC DEHYDROGENASE -LDH	6359850	001	12.50		
02 11 77	CREATINE PHOSPHAKINASE -CPK	6181250	001	14.50		
02 11 77	S-M-A 12 TESTS	6554250	001	21.50		
02 11 77	TRI-IODOTHYRONINE -T-3	ID67000	001	15.50		
02 11 77	T-4	ID39300	001	15.50		
02 11 77	XRY CHEST 1-VIEW	E1D1000	001	20.50		
02 11 77	XRY PORTABLE EQUIPT PER EXAM	E5U3500	001	12.00		
02 11 77	ELECTROCARDIOGRAM --EKG	9063000	001	27.00		
02 11 77	REPLACEMENT CANNULA	J401413	001	4.00		
02 11 77	OXY 02 INCL EQ EX TNT P/H	J200990	016	48.00		
02 11 77	OXYGEN INCL EQUIPMENT SET-UP	J200081	001	8.50		
02 11 77	BLOOD GAS W/02 TENSION 1 SET	6039900	001	37.00		
				DEDUCTIBLE →		

IMPORTANT

THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.

YOUR HOSPITAL PAYMENTS MAY BE ELIGIBLE FOR AN INCOME TAX DEDUCTION. PROMPT PAYMENT WILL INSURE THE BEST CHANCE TO RECEIVE A

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MEADOWS WILLIE A
7235 ARMARILLO ST
HOUSTON •TEXAS 77020

EASTWAY GENERAL HOSPITAL

DATE 02-25-77
PAGE 02

PAT NO 082173867
PAT TYPE 52

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 02-09-77 TIME 07100 A.M. [X] P.M. [ ] S/PS DAILY RATE 73.00
PATIENT AGE: 68 POLICY / GROUP NO.
DISCHARGE DATE 02-21-77 TIME 10135 A.M. [X] P.M. [ ] DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF
ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME
SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 11 77	ARTERIAL PUNCTURE BLOOD GAS	G0640S0	001	16.50		
02 11 77	URINALYSIS CHEMICAL & MICRO	G6450S0	001	5.50		
02 11 77	SERUM OSMOLALITY	G6196S0	001	10.00		
02 11 77	SERUM MAGNESIUM	G3688S0	001	4.00		
02 11 77	COMPLETE BLOOD COUNT CBC	G1704S0	001	8.50		
02 11 77	PROTHROMBIN TIME	G4958S0	001	8.00		
02 11 77	SODIUM FLAME	G5608S0	001	9.00		
02 11 77	POTASSIUM -K	G4762S0	001	8.50		
02 11 77	CHLORIDE	G1484S0	001	8.00		
02 11 77	CO2 COMBINING POWER	G1286S0	001	11.00		
02 11 77	UREA NITROGEN BLOOD BUN	G6410S0	001	8.00		
02 11 77	TRANSAMINASE SGOT	G6252S0	001	11.00		
02 11 77	LATIC DEHYDROGENASE -LDH	G3598S0	001	12.50		
02 11 77	CREATINE PHOSPHAKINASE -CPK	G1812S0	001	14.50		
02 11 77	CPK ISO ENZYMES	G1814T5	001	20.50		
02 11 77	LDH ISO ENZYMES	G3620S0	001	22.50		
02 11 77	XRY PORTABLE EQUIPT PER EXAM	E5U3500	001	12.00		
02 11 77	XRY CHEST 1-VIEW	E1D1000	001	20.50		
02 11 77	INTENSIVE CARE UNIT	A201500	001	175.50		
02 12 77	INTENSIVE CARE UNIT	A201500	001	175.50		
02 13 77	INTENSIVE CARE UNIT	A201500	001	175.50		
02 14 77	PTT	G4438S0	001	9.00		
02 14 77	PROTHROMBIN TIME	G4958S0	001	8.00		
02 14 77	CROSSMATCH	M000700	001	8.50		
02 14 77	COOMBS CROSSMATCH	M000800	001	11.00		
02 14 77	BLOOD TYPING ABO	G101250	001	5.00		
02 14 77	BLOOD TYPING RH FACTOR	G103050	001	4.00		
02 14 77	CROSSMATCH	M000700	001	8.50		
02 14 77	COOMBS CROSSMATCH	M000800	001	11.00		
02 14 77	BLOOD TYPING ABO	G101250	001	5.00		
02 14 77	BLOOD TYPING RH FACTOR	G103050	001	4.00		
				DEDUCTIBLE →		

IMPORTANT

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DATE 02-25-77
PAGE 03

MEADOWS WILLIE A
7235 AMARILLO ST
HOUSTON ,TEXAS 77020

PAT NO 002173867
PAT TYPE 52

EASTWAY GENERAL HOSPITAL

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 02-09-77 TIME 07100 A.M. [X] P.M. [ ] S/PE RM RATE 75.00

PATIENT AGE: 68
POLICY / GROUP NO.
DISCHARGE DATE 02-21-77 TIME 10135 A.M. [X] P.M. [ ] DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME
SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO ENSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 14 77	CROSSMATCH	M000700	001	8.50		
02 14 77	COOMBS CROSSMATCH	M000800	001	11.00		
02 14 77	COOMBS INDIRECT	6173450	001	8.00		
02 14 77	BLOOD TYPING ABO	6101250	002	10.00		
02 14 77	BLOOD TYPING RH FACTOR	6103050	002	8.00		
02 14 77	URINALYSIS CHEMICAL & MICRO	6645050	001	5.50		
02 14 77	URINALYSIS CHEMICAL & MICRO	6645050	001	5.50		
02 14 77	TRANSAMINASE SGOT	6625250	001	11.00		
02 14 77	LATIC DEHYDROGENASE -LDH	6359850	001	12.50		
02 14 77	CREATINE PHOSPHAKINASE -CPK	6181250	001	14.50		
02 14 77	COMPLETE BLOOD COUNT CBC	6170450	001	8.50		
02 14 77	COMPLETE BLOOD COUNT CBC	6170450	001	8.50		
02 14 77	TRANSAMINASE SGOT	6625250	001	11.00		
02 14 77	LATIC DEHYDROGENASE -LDH	6359850	001	12.50		
02 14 77	CREATINE PHOSPHAKINASE -CPK	6181250	001	14.50		
02 14 77	SODIUM FLAME	6560850	001	9.00		
02 14 77	POTASSIUM -K	6476250	001	8.50		
02 14 77	CHLORIDE	6148450	001	8.00		
02 14 77	CO2 COMBINING POWER	6128650	001	11.00		
02 14 77	CULTURE W/SENSITIVITY ROUTINE	6191050	001	19.00		
02 14 77	CULTURE W/SENSITIVITY ROUTINE	6191050	001	19.00		
02 14 77	CULTURE W/SENSITIVITY ROUTINE	6191050	001	19.00		
02 14 77	CULTURE W/SENSITIVITY ROUTINE	6191050	001	19.00		
02 14 77	CULTURE W/SENSITIVITY ROUTINE	6191050	001	19.00		
02 14 77	CULTURE W/SENSITIVITY ROUTINE	6191050	001	19.00		
02 14 77	CULTURE W/SENSITIVITY ROUTINE	6191050	001	19.00		
02 14 77	OXY 02 INCL EQ EX TNT P/H	J200990	004	12.00		
02 14 77	OXY 02 INCL EQ EX TNT P/H	J200990	004	12.00		
02 14 77	OXY 02 INCL EQ EX TNT P/H	J200990	004	12.00		
02 14 77	ELECTROCARDIOGRAM --EKG	Q063000	001	27.00		
02 14 77	ELECTROCARDIOGRAM --EKG	Q063000	001	27.00		
				DEDUCTIBLE →		

IMPORTANT

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MEADOWS WILLIE A
7235 ARMARILLO ST
HOUSTON ,TEXAS 77020

EASTWAY GENERAL HOSPITAL

DATE 02-25-77
PAGE 04

PAT NO 002173867
PAT TYPE 52

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 02-09-77 TIME 07:00 A.M. [X] P.M. [ ] S/R RM. RATE 73.00
PATIENT AGE: 68 POLICY / GROUP NO.
DISCHARGE DATE 02-21-77 TIME 10:35 A.M. [X] P.M. [ ] DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER SELF
ADMITTING DIAGNOSIS POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS 4279 BRADYCARDIA TACHYCARDIA SYNDROME
SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 14 77	KLEENEX PER BOX RX ONLY	HF82601	001	2.00		
02 14 77	GLOVES LATEX STERILE	HT12200	004	10.00		
02 14 77	TOPPER SPONGES EA 4X4	HT99295	004	4.00		
02 14 77	BALECTRODE KIT BALLON PROBE	HA78600	001	79.00		
02 14 77	TED ANTI EMBOLISM STOCKINGS PR	HK67900	001	18.00		
02 14 77	PACEMAKER BATTERY DAILY CHG PT	HH22452	001	21.50		
02 14 77	XRY CHEST 1-VIEW	E1D1000	001	20.50		
02 14 77	INTENSIVE CARE UNIT	A201500	001	175.50		
02 15 77	IPPB & USN SETUP CHANGE-OUT		001	10.00		
02 15 77	IPPB MACH INC DRUG 02 P/TREAT	J503500	002	19.00		
02 15 77	OXY 02 INCL EQ EX TNT P/H	J200990	004	12.00		
02 15 77	XRY PORTABLE EQUIPT PER EXAM	E5U3500	001	12.00		
02 15 77	XRY CHEST 1-VIEW	E1D1000	001	20.50		
02 15 77	KEG RM 60 MIN	B020060	001	27.00		
02 15 77	DRESSINGS TRAY SM	HC86800	001	6.00		
02 15 77	ASEPTO		001	1.00		
02 15 77	ASEPTO		001	1.00		
02 15 77	BOWIE W/CORD		001	16.50		
02 15 77	DISP SUCTION W/COLLECTION		001	5.00		
02 15 77	ANESTH. 60 MIN.	D500360	001	40.50		
02 15 77	ANESTH. EA ADDL. 30 MIN.	D500630	001	15.50		
02 15 77	O.R. 90 MIN.	CA00090	001	156.00		
02 15 77	AIRWAYS PLASTIC RESUSTIBUE	HA18600	001	4.50		
02 15 77	MEDICUT CANNULA NDT PLS ANESTH	HG52700	001	3.50		
02 15 77	PREP TRAY	HH71390	001	6.25		
02 15 77	PREP TRAY	HH71390	001	6.25		
02 15 77	DEX 55 IN D/W 500	F526160	001	8.50		
02 15 77	KEFLIN 1GM	FK07560	010	80.00		
02 1 77	MISC CENTRAL SUPPLY CHG		001	2046.00		
02 15 77	TYLENOL W/CODEINE NO 3 TAB	FY24785	006	3.00		
02 15 77	TUBERCULIN SKIN TEST	GH79100	001	4.00		
					DEDUCTIBLE →	

IMPORTANT

THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.

YOUR HOSPITAL PAYMENT MAY BE ELIGIBLE FOR FAVORABLE TAX DEDUCTION. PROMPT PAYMENT WILL INSURE THE BEST CHANCE TO RECEIVE [illegible]

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7235 ARMARILLO ST
HOUSTON ,TEXAS 77020

DATE 02-25-77
PAGE 05

PAT NO 002173867
PAT TYPE 52

EASTWAY GENERAL HOSPITAL

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT D-T-T: 02-09-77 TIME 07:00 A.M. [X] P.M. [ ]
S/PR RM. RATE 73.00

PATIENT AGE: 68
POLICY / GROUP NO.
DISCHARGED DATE: 02-21-77 TIME 10:35 A.M. [X] P.M. [ ]
DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME

SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 15 77	ATROPINE ANY STR INJ	FB59805	001	2.00		
02 15 77	K-LYTE/CL		008	2.40		
02 15 77	KEFLIN 1GM	FK07560	006	48.00		
02 15 77	VALIUM ANY STRENGTH TAB	FY51385	010	5.00		
02 15 77	VALIUM ANY STR INJ	FY52150	003	10.50		
02 15 77	PHENERGAN ANY STR INJ	FO58300	005	16.25		
02 15 77	TYLENOL W/CODEINE NO 3 TAB	FY24785	011	5.50		
02 15 77	SURFAK CAP 240 MG	FS69160	004	1.00		
02 15 77	SERUM MAGNESIUM	G388050	001	4.00		
02 15 77	SERUM OSMOLALITY	G419650	001	10.00		
02 15 77	ACID FST CONCERT SMEAR &CULTUR	G008050	001	16.50		
02 15 77	ACID FST CONCERT SMEAR &CULTUR	G008050	001	16.50		
02 15 77	ACID FST CONCERT SMEAR &CULTUR	G008050	001	16.50		
02 15 77	POTASSIUM -K	G476250	001	8.50		
02 15 77	SERUM MAGNESIUM	G388850	001	4.00		
02 15 77	SERUM OSMOLALITY	G419650	001	10.00		
02 15 77	LATIC DEHYDROGENASE -LDH	G359850	001	12.50		
02 15 77	CREATINE PHOSPHAKINASE -CPK	G181250	001	14.50		
02 15 77	GRAM STAIN SMEAR	G301450	001	6.00		
02 15 77	CPK ISO ENZYMES	G181475	001	20.50		
02 15 77	LDH ISO ENZYMES	G362050	001	22.50		
02 15 77	FUNGUS DIRECT SMEAR & CULTURE	G264250	001	16.50		
02 15 77	GRAM STAIN SMEAR	G301450	001	6.00		
02 15 77	SPCL CHG FOR HANDLING	G220000	0C1	6.00		
02 15 77	SPCL CHG FOR HANDLING	G220000	001	6.00		
02 15 77	ACID FST CONCERT SMEAR &CULTUR	G008050	001	16.50		
02 15 77	CULTURE W/SENSITIVITY ROUTINE	G191050	001	19.00		
02 15 77	CULTURE W/SENSITIVITY ROUTINE	G191050	001	19.00		
02 15 77	XRY CHEST 1-VIEW	E1D1000	001	20.50		
02 15 77	XRY CHEST 2-VIEWS	E1D1500	001	24.50		
02 15 77	INTENSIVE CARE UNIT	A201500	001	175.50		

IMPORTANT

THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.

[illegible] HOSPITAL PAYMENTS MAY BE ELIGIBLE FOR AN INCOME TAX DEDUCTION. PROMPT PAYMENT WILL INSURE THE BEST CHANCE TO RECEIVE IT.

DEDUCTIBLE →

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DATE 02-25-77
PAGE 06

MEADOWS WILLIE A
7235 AMARILLO ST
HOUSTON •TEXAS 77020

PAT NO 002173867
PAT TYPE 52

EASTWAY GENERAL HOSPITAL

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 02-09-77 TIME 07:00 A.M. [X] P.M. [ ] DAILY RATE 73.00

PATIENT AGE: 68
POLICY / GROUP NO.
DISCHARGE DATE 02-21-77 TIME 10:35 A.M. [X] P.M. [ ] DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME
SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 16 77	FUNGUS DIRECT SMEAR	G264050	001	6.00		
02 16 77	SODIUM FLAME	G560850	001	9.00		
02 16 77	POTASSIUM -K	G476250	001	8.50		
02 16 77	CHLORIDE	G148450	001	8.00		
02 16 77	CO2 COMBINING POWER	G128650	001	11.00		
02 16 77	COMPLETE BLOOD COUNT CBC	G170450	001	8.50		
02 16 77	XRY CHEST 1-VIEW	E1D1000	001	20.50		
02 16 77	ELECTROCARDIOGRAM --EKG	Q063000	001	27.00		
02 16 77	LIDOCAINE 50MG/5CC BRISTO		002	10.00		
02 16 77	DEX 55 IN D/W 500	F526160	001	8.50		
02 16 77	DEX 55 IN D/W 500	F526160	002	17.00		
02 16 77	BURETROL		001	11.00		
02 16 77	DEX 5% IN LACTATED RING 1000	F529230	001	11.00		
02 16 77	LACTATED RING 1000	F571760	001	10.50		
02 16 77	NORMAL SALINE IRRIG 1000CC	F000000	002	14.00		
02 16 77	MVI	FK94845	001	5.75		
02 16 77	DOPRAM 1CC	FF45955	002	3.00		
02 16 77	NARCAN 1CC	0000000	001	5.00		
02 16 77	PENTOTHAL SOD 500 MG	0000000	001	5.00		
02 16 77	SUBLIMAZE 2CC	FS42930	003	9.00		
02 16 77	INNOVAR ANY STRENGTH INJ	FJ49180	003	31.50		
02 16 77	KEFLIN 1GM	FK07560	001	8.00		
02 16 77	AMINOPHYLLINE 500MG IV 20CC	FA83275	001	3.50		
02 16 77	KEFZOL 1GM	FK07925	001	12.50		
02 16 77	MISC DRUG CHG		001	10.50		
02 16 77	PHENERGAN ANY STR INJ	F050300	005	16.25		
02 16 77	AMINOPHYLLINE ANY STR SUPP	FA82475	005	3.00		
02 16 77	TYLENOL TAB 325MG OR 5GR	FY23925	012	3.60		
02 16 77	GARAMYCIN 40 MG/CC 2CC VIAL	FH02560	004	56.00		
02 16 77	KEFLIN 1GM	FK07560	004	32.00		
02 16 77	KEFLEX 250MG CAP	FK07175	012	13.80		
				DEDUCTIBLE →		

IMPORTANT
THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.
[redacted]

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MEADOWS WILLIE A
7235 ARMARILLO ST
HOUSTON ,TEXAS 77020

EASTWAY GENERAL HOSPITAL

DATE 02-25-77
PAGE 07

PAT NO 002173867
PAT TYPE 52

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 02-09-77 TIME 07100 A.M. [X] P.M. [ ] S/PR RM. RATE 73.00

PATIENT AGE: 68 POLICY / GROUP NO.
DISCHARGE DATE 02-21-77 TIME 10135 A.M. [X] P.M. [ ] DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME

SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 16 77	DORIDEN TAB .5 GM	FF48465	006	1.50		
02 16 77	IPPB & USN SETUP CHANGE-OUT		002	20.00		
02 16 77	IPPB MACH INC DRUG 02 P/TREAT	J503500	005	47.50		
02 16 77	ULTRASONIC NEBULIZER	J514058	003	24.00		
02 16 77	OXY 02 INCL EQ EX TNT P/H	J200990	004	12.00		
02 16 77	POSTURAL DRAING BRTH EXER	J509284	001	11.00		
02 16 77	ARTERIAL PUNCTURE BLOOD GAS	G064050	001	16.50		
02 16 77	BLOOD GAS W/02 TENSION 1 SET	G059900	001	37.00		
02 16 77	DEX 55 IN D/W 500	F526160	001	6.50		
02 16 77	INTENSIVE CARE UNIT	A201500	001	175.50		
02 17 77	BLOOD CULTURE	G091650	002	26.00		
02 17 77	BLOOD CULTURE	G091650	002	26.00		
02 17 77	BLOOD CULTURE	G091650	002	26.00		
02 17 77	BREATHING EXERCISOR P/DAY	J500224	001	11.00		
02 17 77	IPPB & USN SETUP CHANGE-OUT		002	20.00		
02 17 77	IPPB MACH INC DRUG 02 P/TREAT	J503500	004	38.00		
02 17 77	ULTRASONIC NEBULIZER	J514058	004	32.00		
02 17 77	OXY 02 INCL EQ EX TNT P/H	J200990	004	12.00		
02 17 77	POSTURAL DRAING BRTH EXER	J509284	002	22.00		
02 17 77	DEMEROL ANY STRENGTH INJ	FE64180	002	4.00		
02 17 77	GARAMYCIN 40 MG/CC 2CC VIAL	FH02560	006	84.00		
02 17 77	DARVON ANY STRENGTH	FE40130	024	12.00		
02 17 77	DOXIDAN CAP	FF51760	006	1.50		
02 17 77	MILK OF MAGNESIA LIQUID DRAM	FL71915	036	10.80		
02 17 77	STIPI STRIP	HT79900	001	2.50		
02 17 77	KLEENEX PER BOX RX ONLY	HF62801	001	2.00		
02 17 77	STIPI STRIP	HT79900	001	2.50		
02 17 77	STIPI STRIP	HT79900	001	2.50		
02 17 77	SUTURE REMOVL TRAY NOT PLS O.R	HK46100	001	6.00		
02 17 77	ANECTINE 500MG FP	0000000	001	3.50		
02 17 77	SEMI PRI ROOM	A102730	001	73.00		
				DEDUCTIBLE →		

IMPORTANT
THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.

YOUR HOSPITAL PAYMENTS MAY BE ELIGIBLE FOR AN INCOME TAX DEDUCTION. PROMPT PAYMENT WILL INSURE THE BEST CHANCE TO RECEIVE A [illegible].

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DATE 02-25-77
PAGE 08

MEADOWS WILLIE A
7235 ARMARILLO ST
HOUSTON TEXAS 77020

PAT NO 00217386?
PAT TYPE 52

EASTWAY GENERAL HOSPITAL

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 02-09-77 TIME 07:00 A.M. [X] P.M. [ ]
S/PR RM. RATE 73.00

PATIENT AGE: 68
POLICY / GROUP NO.
DISCHARGE DATE 02-21-77 TIME 10:35 A.M. [X] P.M. [ ]
DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME

SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 18 77	DEX 55 IN D/W 500	F526160	001	8.50		
02 18 77	KEFLIN 1GM	FK07560	004	32.00		
02 18 77	LIDOCAINE 50MG/5CC BRISTO		001	5.00		
02 18 77	LIDOCAINE 50MG/5CC BRISTO		001	5.00		
02 18 77	DEX 55 IN D/W 500	F526160	001	8.50		
02 18 77	KEFLIN 1GM	FK07560	004	32.00		
02 18 77	PHENERGAN ANY STR INJ	F050300	005	16.25		
02 18 77	VALIUM ANY STR INJ	F?52150	002	7.00		
02 18 77	DEX 55 IN D/W 500	F526160	001	8.50		
02 18 77	DEX 55 IN D/W 500	F526160	001	8.50		
02 18 77	ELECTROENCEPHALOGRAM	Q064750	001	74.00		
02 18 77	EKG DYNAMIC 24-HR	G063320	001	196.50		
02 18 77	UREA NITROGEN BLOOD BUN	G641050	001	9.50		
02 18 77	CREATINIE	G182450	001	9.50		
02 18 77	SGPT GAMMA TRANSPEPTIDASE		001	10.00		
02 18 77	BREATHING EXERCISOR P/DAY	J500224	001	11.50		
02 18 77	AEROSOL INCL EQUIPMENT SET-UP	J500104	001	11.50		
02 18 77	IPPB MACH INC DRUG 02 P/TREAT	J503500	002	20.00		
02 18 77	ULTRASONIC NEBULIZER	J514058	002	17.00		
02 18 77	OXY 02 INCL EQ EX TNT P/H	J200990	004	14.00		
02 18 77	POSTURAL DRAING BRTH EXER	J509284	002	23.00		
02 18 77	SEMI PRI ROOM	A102730	001	73.00		
02 19 77	SEMI PRI ROOM	A102730	001	73.00		
02 20 77	SEMI PRI ROOM	A102730	001	73.00		
02 21 77	K-PAD	HF73375	001	4.50		
02 21 77	BRAIN SCAN 4-VIEWS	IA36850	001	125.50		
02 21 77	CEREBRAL PERFUSION	IA23900	001	67.50		
02 21 77	XRY CHEST 2-VIEWS	E1D1500	001	30.50		
02 21 77	AEROSOL INCL EQUIPMENT SET-UP	J500104	001	11.50		
02 21 77	ULTRASONIC NEBULIZER	J514058	003	25.50		
02 21 77	POSTURAL DRAING BRTH EXER	J509284	002	23.00		

IMPORTANT

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[illegible] MAY BE ELIGIBLE FOR ANY INCOME TAX DEDUCTION. PROMPT PAYMENT WILL ENSURE THE BEST ASSISTANCE TO RECEIVE IT.

DEDUCTIBLE →

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MEADOWS WILLIE A
7235 AMARILLO ST
HOUSTON ,TEXAS 77020

EASTWAY GENERAL HOSPITAL

DATE 02-25-77
PAGE 09

PAT NO 002173867
PAT TYPE 52

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE: 02-09-77 TIME 07:00 A.M. [X] P.M. [ ] E/R INCL RATE 73.00
PATIENT AGE: 68 POLICY / GROUP NO.
DISCHARGE DATE: 02-21-77 TIME 10:35 A.M. [X] P.M. [ ] DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME

SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
02 21 77	AEROSOL INCL EQUIPMENT SET-UP	J500104	001	11.50		
02 21 77	ULTRASONIC NEBULIZER	J514058	004	34.00		
02 21 77	ACTIVE DAILY LIVING EVALUAT	L200050	002	37.00		
02 21 77	ACTIVE DAILY LIVING EVALUAT	L200050	001	18.50		
02 21 77	PHISOHEX 1 OZ	0000000	005	5.00		
02 21 77	CHLOROMYCETIN CBM 10Z	F000000	001	6.50		
02 21 77	VISTARIL 50MG CAP	FY92680	012	3.60		
02 21 77	NOCTEC CAP 500 MG OR 7.5 GR	FM95705	002	0.50		
02 21 77	OILOR TAB	FF19090	020	5.00		
02 21 77	LARODOPA 0.5GRAM TAB		019	4.75		
02 21 77	SURFAK CAP 240 MG	FS69160	002	0.50		
02 21 77	K-PAD	HF73375	001	4.50		
02 21 77	ABDOMINAL BINDER HOSP USE	HA06800	001	20.50		
02 21 77	LARODOPA 0.5GRAM TAB		012	3.00		
02 21 77	MISC DRUG CHG		020	5.00		
02 21 77	SURFAK CAP 240 MG	FS69160	006	1.50		
02 21 77	ONE MODALITY	L000100	001	11.50		
02 21 77	AEROSOL INCL EQUIPMENT SET-UP	J500104	001	11.50		
02 21 77	PHISOHEX 1 OZ	0000000	004	4.00		
02 21 77	MISC DRUG CHG		001	8.50		
02 21 77	OILOR TAB	FF19090	010	2.50		
02 21 77	FUNGUS DIRECT SMEAR	G264050	003	22.50		
02 21 77	AEROSOL INCL EQUIPMENT SET-UP	J500104	001	11.50		
02 21 77	ULTRASONIC NEBULIZER	J514058	001	8.50		
02 21 77	POSTURAL DRAING BRTH EXER	J509284	001	11.50		
02 21 77	K-PAD	HF73375	001	4.50		
	TOTAL			7710.95		
				DEDUCTIBLE →		
				7710.95		

IMPORTANT
THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.

YOUR HOSPITAL EXPERIENCE MAY BE ELIGIBLE FOR AN INCOME TAX DEDUCTION. PROMPT PAYMENT WILL ENSURE THE BEST CHANCE TO RECEIVE...

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MEADOWS WILLIE A
7235 ARMARILLO ST
HOUSTON TEXAS 77020

DATE 02-25-77
PAGE 01

PAT NO 002173867
PAT TYPE 52

EASTWAY GENERAL HOSPITAL

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 02-09-77 TIME 07:00 A.M. [X] P.M. [ ] R/R RM. RATE 73.00

PATIENT AGE: 68 POLICY / GROUP NO.
DISCHARGE DATE 02-21-77 TIME 10:35 A.M. [X] P.M. [ ] DAYS STAY 12

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS
POSSIBLE HEART BLOCK
DISCHARGE DIAGNOSIS
4279 BRADYCARDIA TACHYCARDIA SYNDROME

SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY.	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
	SUMMARY OF CHARGES					
	ACCOMMODATION DAYS RATE					
	SEMI PRIVATE 4 73.00			292.00	0.00	292.00
	ICU/CCU 8			1404.00	0.00	1404.00
	OPERATING ROOM			156.00	0.00	156.00
	RECOVERY ROOM			27.00	0.00	27.00
	IV SOLUTIONS			132.50	0.00	132.50
	EMERGENCY ROOM			20.50	0.00	20.50
	LABORATORY			1140.50	0.00	1140.50
	EKG			358.50	0.00	358.50
	EEG AND ECHO			74.00	0.00	74.00
	RADIOLOGY-DIAGNOSTIC			197.50	0.00	197.50
	PHARMACY			501.20	0.00	501.20
	ISOTOPES AND SCANS			193.00	0.00	193.00
	ANESTHESIOLOGY			56.00	0.00	56.00
	INHALALATION THERAPY			767.50	0.00	767.50
	PHYSICAL THERAPY			67.00	0.00	67.00
	CENTRAL SUPPLY AND DRESSINGS			2323.75	0.00	2323.75
	OTHERS			0.00	0.00	0.00
	TOTAL CHARGES			7710.95	0.00	7710.95
	CASH PAYMENTS AND AR ADJUSTMENTS			0.00	0.00	0.00
	TOTAL			7710.95	0.00	7710.95
				DEDUCTIBLE →	0.00	0.00
				7710.95	0.00	7710.95

IMPORTANT
THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.

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ITEM 4. REPLACEMENT BILL OF WILLIE A. MEADOWS

MEADOWS WILLIE ALFORD
7235 AMARILLO ST
HOU ,TX 77020

EASTWAY GENERAL HOSPITAL

DATE 01-17-78
PAGE 01

PAT NO 002252708
PAT TYPE 52
****
* FINAL BILL *
****

PATIENT NAME: MEADOWS WILLIE ALFORD ADMIT DATE 12-30-77 TIME 10:40 A.M. ☐ P.M. ☐ U/M Rm. RATE 82.00

PATIENT AGE: 69 POLICY / GROUP NO. DISCHARGE DATE 01-04-78 TIME 11:32 A.M. ☒ P.M. ☐ DAYS STAY 5

POLICY HOLDER RELATIONSHIP TO POLICY HOLDER
SELF

ADMITTING DIAGNOSIS DISCHARGE DIAGNOSIS
PACEMAKER FAILURE

SURGICAL PROCEDURE DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
12 30 77	O.R. 60 MIN.	CA00060	001	145.00		
12 30 77	ANESTH. 60 MIN.	D500360	001	50.50		
12 30 77	MISC CENTRAL SUPPLY CHG		001	3.25		
12 30 77	ELECTROCARDIOGRAM --EKG	Q063000	001	27.00		
12 30 77	SEMI PRI ROOM	A102730	001	82.00		
12 31 77	URINALYSIS CHEMICAL & MICRO	G645050	001	7.50		
12 31 77	SODIUM FLAME	G560850	001	10.00		
12 31 77	POTASSIUM -K	G476250	001	11.50		
12 31 77	CHLORIDE	G148450	001	11.00		
12 31 77	CO2 COMBINING POWER	G128650	001	15.00		
12 31 77	NORMAL SALINE IRRIG 1000CC	F000000	001	6.00		
12 31 77	D5L/R 1000 CC	F529230	001	12.00		
12 31 77	KEFLIN 1GM	FK07560	001	8.00		
12 31 77	S/W IRRIGATION 1000 CC	F000000	001	8.00		
12 31 77	XRY ABDOMEN 1-VIEW	E0A1500	001	21.00		
12 31 77	XRY CHEST 1-VIEW	E1D1000	001	21.50		
12 31 77	EKG ELECTRODES NOT PLUS EKG CG		003	4.95		
12 31 77	AIRWAYS PLASTIC RESUSTIBUE	HA16600	001	6.00		
12 31 77	MEDICUT CANNULA NOT PLS ANESTH	HG52700	001	5.00		
12 31 77	PREP TRAY	HM71390	001	7.50		
12 31 77	ASEPTO		001	1.00		
12 31 77	BOWIE W/CORD		001	16.50		
12 31 77	DISP SUCTION W/COLLECTION		001	5.00		
12 31 77	SHAVE PREP		001	1.50		
12 31 77	MISC CENTRAL SUPPLY CHG		001	0.60		
12 31 77	ADAPTIC DRESSING 3X3	HS14610	001	3.00		
12 31 77	ADAPTIC DRESSING 3X3	HS14610	001	3.00		
12 31 77	MISC CENTRAL SUPPLY CHG		001	2304.50		
12 31 77	SEMI PRI ROOM	A102730	001	82.00		
01 01 78	SEMI PRI ROOM	A102730	001	82.00		
01 02 78	XYLOCAINE VISCOUS 100CC	FZ28175	002	13.50		
				DEDUCTIBLE →		

IMPORTANT

THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.

WHEN PAID, YOUR HOSPITAL EXPENSES NOT COVERED BY INSURANCE MAY BE ELIGIBLE FOR A TAX DEDUCTION.

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MEADOWS WILLIE ALFORD
7235 AMARILLO ST
HOU TX 77020

EASTWAY GENERAL HOSPITAL

DATE 01-17-78
PAGE 02

PAT NO 002252708
PAT TYPE 52
****
* FINAL BILL *
****

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 12-30-77 TIME 10:40 A.M. ☐ P.M. ☐ E/R OR RM RATE 82.00
PATIENT AGE: 69
POLICY / GROUP NO.
DISCHARGE DATE 01-04-78 TIME 11:32 A.M. ☒ P.M. ☐ DAYS STAY 5

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER: SELF
ADMITTING DIAGNOSIS: PACEMAKER FAILURE
DISCHARGE DIAGNOSIS
SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
01 02 78	SEMI PRI ROOM	A102730	001	82.00		
01 03 78	SEMI PRI ROOM	A102730	001	82.00		
01 04 78	ELECTROCARDIOGRAM --EKG	0063000	001	27.00		
01 04 78	ANCEF 500MG INJ	F805900	001	8.50		
01 04 78	ANCEF 1GM INJ	F805910	001	16.00		
01 04 78	ELECTROCARDIOGRAM --EKG	0063000	001	27.00		
01 04 78	CULTURE W/SENSITIVITY ROUTINE	G191050	001	22.00		
01 04 78	ADAPTIC DRESSING 3X3	HS14610	001	3.00		
01 04 78	TOPPER SPONGES EA 4X4	HT99245	002	3.00		
01 04 78	TYLENOL C/COD TAB ANY	FY24785	008	4.00		
01 04 78	TYLENOL TAB 325MG OR 5GR	FY23925	014	4.20		
01 04 78	ANCEF 500MG INJ	F805900	020	170.00		
01 04 78	ANCEF 500MG INJ	F805900	001	8.50		
01 04 78	DULCOLAX TAB	0000000	004	1.40		
01 04 78	NOCTEC CAP 250MG	FM95550	010	5.00		
01 04 78	HYDRODIURIL 50MG TAB		009	2.25		
01 04 78	MISC DRUG CHG		051	12.75		
01 04 78	K-LYTE/CL PACKETT		015	6.00		
01 04 78	EKG DYNAMIC 24-HR	0063320	001	196.50		
01 04 78	ELECTROCARDIOGRAM --EKG	0063000	001	27.00		
01 04 78	TOPPER SPONGES EA 4X4	HT99245	001	1.50		
01 04 78	SUTURE REMOVL TRAY NOT PLS O.R	HK46130	001	8.50		
01 04 78	ANCEF 500MG INJ	F805900	-01	8.50-		
01 04 78	QUINIDINE SULFATE 3GR TAB	FP66360	024	7.20		
01 04 78	ANCEF 1GM INJ	F805910	001	16.00		
	TOTAL			3710.10		

IMPORTANT
THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE CONTRACT.
WHEN PAID, YOUR HOSPITAL EXPENSES NOT COVERED BY INSURANCE MAY BE ELIGIBLE FOR A TAX DEDUCTION

DEDUCTIBLE →
3710.10

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MEADOWS WILLIE ALFORD
7235 AMARILLO ST
HOU TX 77020

EASTWAY GENERAL HOSPITAL

DATE 01-17-78
PAGE 01

PAT NO 002252708
PAT TYPE 52
****
* FINAL BILL *
****

PATIENT NAME: MEADOWS WILLIE ALFORD
ADMIT DATE 12-30-77 TIME 10:40 A.M. [ ] P.M. [ ] R/M RM. RATE 82.00
PATIENT AGE: 69 POLICY / GROUP NO.
DISCHARGE DATE 01-04-78 TIME 11:32 A.M. [X] P.M. [ ] DAYS STAY 5

POLICY HOLDER
RELATIONSHIP TO POLICY HOLDER
SELF
ADMITTING DIAGNOSIS
DISCHARGE DIAGNOSIS
PACEMAKER FAILURE
SURGICAL PROCEDURE
DATE

PLEASE DETACH AND RETURN THIS PORTION WITH YOUR PAYMENT TO INSURE PROPER CREDIT TO YOUR ACCOUNT.

SERVICE DATE	DESCRIPTION	CHARGE CODE	QNTY	TOTAL CHARGES	ESTIMATED INSURANCE	PATIENT AMOUNT
	SUMMARY OF CHARGES					
	ACCOMMODATION DAYS RATE					
	SEMI PRIVATE 5 82.00			410.00	410.00	0.00
	OPERATING ROOM			145.00	145.00	0.00
	IV SOLUTIONS			28.00	28.00	0.00
	LABORATORY			77.40	77.00	0.00
	EKG			304.50	304.50	0.00
	RADIOLOGY-DIAGNOSTIC			42.50	42.50	0.00
	PHARMACY			274.80	274.80	0.00
	ANESTHESIOLOGY			50.50	50.50	0.00
	CENTRAL SUPPLY AND DRESSINGS			2377.80	2377.80	0.00
	OTHERS			0.00	0.00	0.00
	TOTAL CHARGES			3710.10	3710.10	0.00
	CASH PAYMENTS AND AR ADJUSTMENTS			0.00	0.00	0.00
	TOTAL			3710.10	3710.10	0.00
				DEDUCTIBLE →	124.00	124.00
				3710.10	3586.10	124.00

30000 Repl

IMPORTANT
THE INSURANCE BENEFITS SHOWN ABOVE ARE SUBJECT TO REVIEW BY THE INSURANCE COMPANY AND MAY BE CHANGED IF NOT IN ACCORD WITH THE COMPANY.
WHEN PAID, YOUR HOSPITAL EXPENSES NOT COVERED BY INSURANCE MAY BE ELIGIBLE AS A TAX DEDUCTION.

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Appendix 2

MATERIAL RELATED TO HEARING

ITEM 1. LETTER FROM DR. BRENDAN PHIBBS, CHIEF OF MEDICINE AND DIRECTOR OF CARDIOLOGY, KINO COMMUNITY HOSPITAL, TUCSON, ARIZ., TO SENATOR JOHN GLENN, DATED SEPTEMBER 14, 1982

DEAR SENATOR GLENN: During the hearings before the Committee on Aging last week, you asked some questions I wanted to respond to, but time was getting late and I didn't see any point in prolonging things. Specifically, you wanted to know if the concern of many physicians nationwide about inappropriate insertion of pacemakers was based on "hindsight." I can tell you categorically that it is not; the leading authorities in cardiac arrhythmias all over the country have reviewed hundreds of these cases, and they are all concerned. It's not a question of new medical knowledge invalidating previous concepts, but rather a case of insertion of pacemakers for minor disorders of the heartbeat that have been known to be harmless for decades. These are not borderline or "grey area" differences; I was referring, as were the other physicians, to violations of standards that can only be called flagrant.

I didn't want to get into another argument with my friend, Sy Furman, when he became defensive about the figures on the Maryland study, but you'll notice that nobody on the panel disagreed when I made the observation that inevitably, without exception, any procedure that generates profit will be abused by an unscrupulous minority of our profession and that always, without exception, we have had to organize peer review and quality control standards to stop this kind of abuse. An enormously profitable procedure like pacemaker implantation, which is technically pretty simple, is absolutely going to generate overutilization and abuse in the absence of some kind of control. To assume that it would not would be about like assuming that an 18-year-old heiress decked in mink and diamonds could wander through the darkest part of the New York slums unmolested. It would be a complete reversal of anything that's ever happened in the history of the medical profession of this country and, in fact, such an assumption would be incredibly naive.

The tissue committee approach, which I mentioned to the committee, has been very valuable, but the problem is that in the setting of invasive cardiology, including pacemaker insertion, we do not have any tissue to study to validate the procedure. It is therefore essential that standards be promulgated, and this is really rather easy to do. The standards put into effect by Friedman and his group at Downstate University in Brooklyn (JAMA, August 14, 1981) are very reasonable and, in fact, if anything, on the side of being liberal. Despite this, they had a very salutary effect in their region.

Since the Government has become an enormous purchaser of medical services, it's certainly going to be incumbent on the Government to look to the appropriateness of the services it's paying for, because I can tell you from bitter experience that uncontrolled and uncritical remuneration is going to generate a level of abuse that can put the whole medicare program in jeopardy. As one who has been a physician for over 40 years, it really saddens me to say this but, having had to preside on lots of disciplinary committees, tissue committees, professional review committees, and the like, I can assure you it is the hard truth.

In a book I wrote not long ago, I paraphrased Lord Acton to say that "enormous profits corrupt enormously," and I'm afraid that's true through all strata of our society. Anyway, I think some standards can be promulgated and put into effect through the PSRO organization, which would bring the whole thing to a salutary halt.

Respectfully,

BRENDAN PHIBBS, M.D., F.A.C.C.

ITEM 2. LETTER FROM THOMAS P. FINLEY, EXECUTIVE DIRECTOR, GREATER SOUTHERN ARIZONA PROFESSIONAL STANDARDS REVIEW ORGANIZATION, TUCSON, ARIZ., TO SENATOR JOHN HEINZ, CHAIRMAN, U.S. SENATE SPECIAL COMMITTEE ON AGING, DATED OCTOBER 15, 1982

DEAR SENATOR HEINZ: Thank you for furnishing this organization with a copy of your report involving fraud, waste, and abuse in the pacemaker industry. Needless to say, the contents of this report are shocking even to those of us who have been actively dealing with this problem for some time.

As a professional organization vitally concerned with the quality and utilization of medical resources, we appointed a subcommittee to study various cardiology procedures. It was the charge to this committee to develop criteria to address a variety of procedures. The situation studied included insertion of permanent pacemakers, cardiac catheterization and coronary bypass surgery. Our criteria subcommittee solicited input from all area cardiologists to assist in the development of the criteria sets.

The material developed has been furnished to all area hospitals and are utilized in assessing the medical necessity and appropriateness of these procedures. In addition, representatives of this organization conduct frequent onsite monitoring of randomly selected cases to verify the application of and compliance with these criteria sets.

When we became aware of the activities of the Public Citizen's Health Research Group in Maryland, we voluntarily submitted copies of our criteria sets to the various PSRO's within that State. We also received a request from the PSRO in South Carolina for this material. Most recently, we were contacted by Dr. Zelinger, senior medical officer in the Health Standards and Quality Bureau of the Health Care Financing Administration who also requested this material.

As a professional standards review organization, we are not involved in cost and charge factors since this falls within the province of the fiscal intermediary.

As stated in the committee report, the intermediaries are responsible for determining reimbursement to hospitals on the basis of reasonable costs. Another extremely important requirement of the medicare program is the application of the "prudent buyer concept."

The fascinating sales techniques involved in the sale of pacemakers are incredible. While it is the physician community which is the object of the salespersons affections, it is the hospital which does the actual purchasing and billing for these devices. Obviously since the hospital is interested in maintaining a competitive medical staff, they will, in the vast majority of cases purchase whatever items the physicians prefer.

To correct a problem of this magnitude will require a concerted and well orchestrated effort by government, the private health insurance industry, physicians, and hospitals.

Certainly, the American College of Cardiologists should develop minimum standards of qualifications and expertise which a physician must meet in order to perform this procedure. Intermediaries should immediately undertake a concerted effort to examine and, where appropriate, disallow unreasonable or excessive charges for these devices. Hospitals should be required to identify the specific charge for a permanent pacemaker on the medicare billing form. Purchasing agents employed by hospitals should be instructed to purchase permanent pacemakers based upon the quality of the device and reasonable cost.

While overutilization or improper utilization are significant problems, the paramount abuse is in the highly suspect marketing techniques employed and the subsequent unreasonable markups in the hospital setting.

In conclusion, several mechanisms exist to deal with this problem, however, they apparently are not being properly applied. Medicare and medicaid fiscal intermediaries must clamp down on these abuses through the application of the reasonable cost and prudent buyer provisions of existing law. The private sector including commercial health insurance underwriters and various Blue Cross/Blue Shield programs must aggressively pursue these abuses. The physician community must act forcefully to bring about positive change within its ranks through the development of meaningful protocols working with the American College of Cardiologists. Those PSRO's which have not developed meaningful criteria for this procedure should do so without delay. Once developed, they must be adhered to.

You and your committee are to be congratulated for your aggressive investigation of this scandalous situation. We appreciate the opportunity to comment on this matter and we stand ready to help you in your efforts to eradicate this immoral and repugnant situation.

Cordinally,

THOMAS P. FINLEY.

ITEM 3. LETTER FROM MERRITT W. JACOBY, EXECUTIVE DIRECTOR, MEDICARE A ADMINISTRATION, BLUE CROSS AND BLUE SHIELD ASSOCIATION, CHICAGO, ILL., TO SENATOR JOHN HEINZ, CHAIRMAN, U.S. SENATE SPECIAL COMMITTEE ON AGING, DATED NOVEMBER 5, 1982

DEAR SIR: We have reviewed the committee's September 1982 information paper on fraud, waste, and abuse in the medicare pacemaker industry. We support the committee's efforts in this area and offer the following comments.

As an intermediary, we have been aware of some problems with replacement of warrantied pacemakers. Basically, the few problems we've seen involve situations like this: A physician will conclude that a pacemaker is not functioning properly and will replace it. The manufacturer then tests the allegedly defective pacemaker and finds nothing wrong. Then the situation becomes one of the physician's opinion versus the manufacturer's.

The medicare part A intermediary manual (HIM 13, section 3153D) states, in part:

"Similarly, where a defective medical device such as a cardiac pacemaker is replaced under a warranty, hospital or other provider services . . . are covered despite the warrantor's liability. With respect to the device itself, the following rules apply: If the device is replaced free of charge by the warrantor, no program payment may be made, since there was no charge involved. If, however, the device was not replaced by the manufacturer . . . payment may be made for the replaced device."

As you can see, in a situation such as the one described above, the medicare program has paid for both the original and the replacement pacemakers. Intermediaries are required to follow Health Care Financing Administration (HCFA) policies and instructions and have no authority unilaterally to pursue resolutions to situations like this. We do consult with and make recommendations to HCFA as opportunities and needs present themselves.

From the intermediary perspective, we have identified the following problems:

Medicare program instructions for the coverage of pacemakers, replacements and pacemaker-related services do not call for intermediaries to deal with most of the problems identified in the use of pacemakers.

Intermediaries do not have the authority to limit medicare reimbursement of pacemakers beyond HCFA's general instructions.

Medicare general instructions to intermediaries do not allow for enforcement of pacemaker manufacturer warranties.

Physicians control pacemaker replacement decisions, but are not required to justify them under the medicare program.

We believe the Department of Health and Human Services should:

Develop expanded and more stringent general instructions for the coverage of pacemakers, replacements, and related services.

Establish and instruct intermediaries to implement pacemaker charge screens and reimbursement limits.

Determine how best to deal with enforcement of pacemaker manufacturers' warranties.

Require physicians to document the medical necessity for all pacemaker replacements billed to the medicare program.

I would also like to comment briefly on our activities as private health care underwriters with respect to pacemakers. We are aware of the potential for misutilization of pacemaker benefits, and will be reviewing it in the context of our medical necessity program initiative. The primary objective is to determine appropriate criteria for the proper use of pacemakers. Also, we are conducting a survey of Blue Cross and Blue Shield plans to identify differences in pacemaker reimbursement policies and to discover how pacemaker problems can be mitigated. Our intention is to formulate policy guidance for the plans. Both of these activities should result in improved control of pacemaker claims.

We are available to meet with you and your staff or provide other assistance. Thank you for giving us the opportunity to comment.

Very truly yours,

MERRITT W. JACOBY.

ITEM 4. LETTER FROM GLENN A. SHIMMEL, ASSISTANT VICE PRESIDENT, MEDICARE PROGRAMS, BLUE CROSS AND BLUE SHIELD OF SOUTH CAROLINA, COLUMBIA, S.C., TO SENATOR JOHN HEINZ, CHAIRMAN, U.S. SENATE SPECIAL COMMITTEE ON AGING, DATED OCTOBER 21, 1982

DEAR SENATOR HEINZ: I appreciate your recent letter and information paper concerning "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry." As you noted, I do indeed have an interest in this area, and am pleased to share my thoughts with you.

As long as the pacemakers are billed through the hospitals to part A, the inflated costs are simply passed through and paid as just that: inflated costs. There is no compelling reason why pacemakers cannot be treated as durable medical equipment and billed to part B carriers where payment would be established through the reasonable charge mechanism.

Understanding that regional economic differences must be taken into consideration, there is no reasonable explanation for the 300 percent spread in physician charges for implantation. In South Carolina, for example, the prevailing surgical fee paid for implantation is $791. As you know, elsewhere charges range over $2,500.

The real problem in medicare reimbursement is the wide variance in contractor program administration from State to State. Evidence exhibit 1,[1] which graphically demonstrates significant differences in payment for parenteral and enteral nutrition therapy between South Carolina and Chicago. Here again, as in pacemakers, the bulk of the dollars for this treatment is being paid by medicare.

Our concerns over waste and abuse in medicare extends to the double payments we make to radiologists. Curtailing this abuse would save millions in medicare funds. See my letter to Tera Younger, exhibit 2,[1] and the monotonous response, exhibit 3.[1]

We have also addressed the issue of reimbursement to ambulatory surgical centers, see exhibit 4.[1] The short sightedness in developing these payment procedures will enable physicians to make windfall profits; and surgi-center factories will appear on every street corner.

While we have problems, there are solutions. The health care system must have inherent reimbursement reasonableness. In order to achieve this end, intermediaries and carriers must receive adequate utilization review funding in order to look closer at apparent fraud and abuse situations.

The core of HCFA should be dedicated to two areas: First, is the reasonableness of payment . . . benefits administration, second is the budget process. All other HCFA activity should be ancillary.

We will be happy to assist in any way in order to impact on the fraud, waste, and abuse evident in the Federal programs.

Sincerely,

GLENN A. SHIMMEL.

ITEM 5. LETTER FROM THOMAS A. LEVIN, PRESIDENT, BLUE CROSS AND BLUE SHIELD OF NEW MEXICO, ALBUQUERQUE, N. MEX., TO SENATOR JOHN HEINZ, CHAIRMAN, U.S. SENATE SPECIAL COMMITTEE ON AGING, DATED OCTOBER 28, 1982

DEAR SENATOR HEINZ: Thank you for forwarding the report of the U.S. Senate Special Committee on Aging entitled "Fraud, Waste, and Abuse in the Medicare Pacemaker Industry."

The report prompted New Mexico Blue Cross and Blue Shield to conduct a study of pacemakers implanted in medicare and Blue Cross subscribers in New Mexico. Our study, based on a small nonrandom sample of claims from the first quarter of 1982, corraborated certain findings of your committee. Pacemaker charges varied between $2,434 and $7,190, with the average being $4,800. However, we were unable to discern functional differences among the pacemakers which may have contributed to the disparity in costs. Associated charges included average hospital charges of about $10,000 and average physician charges of $1,160.

At this time we do not have any information about replacement of pacemakers under warranty, poor performance of some pacemakers, or improper enticements to encourage sales. It is very difficult for us to evaluate overutilization until the medical profession has reached a more clear consensus on when pacemakers should be implanted and when they are not effective.

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[1] Retained in committee files.

Your committee's report was very informative and shed light on an increasingly common and expensive procedure. I would appreciate any more information the Special Committee develops.

Thank you for the opportunity to comment on your report.

Sincerely,

THOMAS A. LEVIN.

ITEM 6. DEPARTMENT OF HEALTH AND HUMAN SERVICES DRAFT AUDIT REPORT, SEPTEMBER 3, 1982

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

SEP 3 1982

NOTE TO CAROLYNE DAVIS, Ph.D
BOB RUBIN, M.D.
ED BRANDT, M.D.

I have attached a copy of the Inspector General's "OIG Draft Audit Report - more efficient procurement of heart pacemakers could result in Medicare savings of over $64 million annually (ACN 08-22608)". The Inspector General's findings warrant your closest scrutiny.

While the draft report focuses on Medicare, it may well have inplications for other of our programs. For that reason I am asking Dr. Davis to coordinate a task force of HCFA, ASPE, and PHS staff to promptly analyze the findings and advise me of any actions we can take. Please feel free to call on the Inspector General during your deliberations.

Dick Schweiker

Richard S. Schweiker
Secretary

BEST COPY AVAILABLE

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Memorandum

Date

From Richard P. Kusserow
Inspector General

Subject OIG Draft Audit Report - More Efficient Procurement of Heart Pacemakers Could Result in Medicare Savings of Over $64 Million Annually (ACN 08-22608)

To Carolyne K. Davis, Ph.D
Administrator
Health Care Financing Administration

This draft report summarizes the results of a study we made of the prices being paid by Medicare for cardiac pulse generators --commonly known as heart pacemakers. We compared the prices paid for heart pacemakers by hospitals for Medicare patients (and ultimately reimbursed by that program) to the prices for which the same units were available to Federal agencies under GSA's multiple award Federal Supply Schedule. The bulk of the purchases under such schedule contracts are made by VA hospitals. For the purpose of our analyses we used only those costs associated with the prices paid for individual pacemaker units. We did not compare prices paid for the necessary pacemaker leads and any associated medical or administrative expenses. Our review was made on site at 25 hospitals in Arizona, California, Colorado, Florida, Georgia, North Carolina, North Dakota, Tennessee, Texas, and Utah. Since most pacemaker implants involve elderly patients, we concentrated the bulk of our review in the sunbelt area of the country since a higher percent of the population there is elderly.

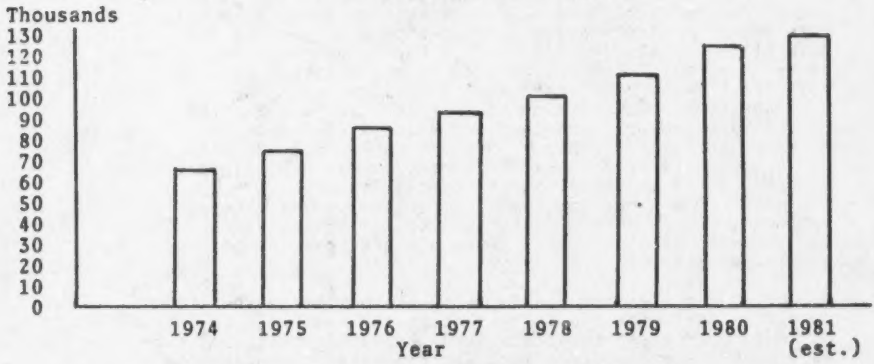
We compared prices for 2,804 pacemakers bought by these 25 hospitals that were available through the GSA Schedule contracts. We found that these hospitals (and ultimately Medicare) had paid an average of $3,424 each for pacemakers identical in make and model to those available under the Schedule contracts for an average of $2,833 each. If arrangements could be made whereby Medicare reimbursements for pacemakers could be made at the same or similar prices as those shown on the Schedule contracts, we estimate that annual savings to Medicare of $64 million would result.

Background

Since about 1960, heart pacemakers have been used by physicians to combat heart diseases common with older people. The pacemaker system consists of a microelectronic module sealed in a small container weighing one to two ounces that is implanted in the patient's chest just below the skin and connected to the heart by a pacemaker lead. A lead is an insulated wire with an electrode tip carrying electrical signals between the pacemaker and the heart, both stimulating and sensing the heart's activity.

An estimated 130,000 pacemakers were implanted in patients in the U.S. in calendar year 1981, more than double the number from just seven years earlier. It may be assumed that these totals will continue to increase as the elderly population continues to increase.

Pacemaker Unit Sales in the United States
1974 through 1981 (Note)



The cost of a pacemaker varies from about $2,000 to $4,000 depending on the brand and model. The most expensive are new multi-programmable models which allow physicians to program implanted pacemakers to any prescription. Leads are purchased separately and cost about $300. Total sales for all pacemakers sold in the U.S. in fiscal year 1982 was about $465 million (Note). The average age of a patient having a pacemaker implant is about 70 years. We estimate that the costs of over 80 percent of all pacemaker implants in the U.S. are covered by Medicare.

Note: Source: Kidder, Peabody & Co., Inc. Cardiac Pacemaker Industry Analysis, January 22, 1981

According to a report on the pacemaker industry by an economic research organization (note) five entities dominate the market. Sales figures for fiscal year 1981 follow:

Manufacturer	Units Sold
Medtronic, Inc., Minneapolis, Minnesota	52,500
Intermedics, Inc., Freeport, Texas	25,000
Cordis Corporation, Miami, Florida	16,000
Cardiac Pacemakers, Inc., St. Paul, Minnesota	15,000
Pacesetter Systems, Inc., Sylmar, California	14,000
All others	7,500
	130,000

All of these major manufacturers plus several others are covered by the GSA Federal Supply Schedule which is effective from April 1, 1981 to September 30, 1982. Work is underway to have a similar Federal Supply Schedule available for use after October 1, 1982.

DISCUSSION OF FINDINGS

Prices paid by Medicare significantly exceed Federal Supply Schedule prices

As mentioned previously, we visited 25 hospitals that purchased 3,694 pacemakers for Medicare recipients (between April 1, 1981 and March 31, 1982). The GSA Schedule contracts during that same period listed 2,804 of the 3,694 units bought by these hospitals (76 percent). Examples of differences in prices paid by the hospital(s) to that available to users of the Federal Supply Schedule for several popular models follow:

Manufacturer	Model	Prices	
		Hospital	FS Schedule
Medtronic	Spectrax 5984	$3,395	$2,875
	Spectrax 5985	3,195	2,875
Intermedics	Cyberlith 253-07	3,295	2,800
	Cyberlith 259-01	3,895	3,300
Cordis	336 A	3,350	2,676
	337 A	3,250	2,593
Cardiac	Microlith P(0505)	2,895	2,316

Note: Source: Kidder, Peabody & Co., Inc. Cardiac Pacemaker Industry Analysis, January 22, 1981

Page 4 - Carolyne K. Davis, Ph.D

As shown by the following summary, prices paid by hospitals and charged to Medicare exceed those obtainable under the Schedule contracts by an average of 17.26 percent.

State	No. of hospitals visited	No. of pacemakers (Note)	Average hospital price	Average schedule price	Savings percentage through schedule contract
Arizona	3	310	$3,417	$2,810	17.8%
California	3	406	3,507	2,937	16.3
Colorado	4	213	3,278	2,760	15.8
Florida	2	293	3,614	2,963	18.0
Georgia	1	57	3,260	2,749	15.7
North Carolina	1	56	3,461	2,898	16.3
North Dakota	2	74	3,186	2,682	15.8
Tennessee	1	151	3,557	2,753	22.6
Texas	5	921	3,378	2,776	17.8
Utah	3	323	3,396	2,890	14.9
Totals	25	2,804	$3,424	$2,833	17.26%

Some sources have argued that pacemaker manufacturers would not offer Medicare similar prices as those offered under the GSA Federal Supply Schedule contracts since Medicare represents more than 80 percent of the domestic pacemaker market whereas procurements under the Schedule contracts (mostly to VA hospitals) are less than 5 percent. We believe these manufacturers do, in fact, have room to offer more favorable prices.

Note: These are not all of the pacemakers implanted by the hospitals. Rather these are the pacemakers (same manufacturer and model number) that were available under the Schedule contracts.

o Based solely upon a cursory glance at the published financial statements of two of the largest manufacturers (Medtronic, Inc. and Intermedics, Inc.), 1981 net earning figures were $41.9 million and $16.2 million, respectively. While these are only indicators, note should be made of a statement in a stockbroker's brief on Intermedics: ". . . Since state-of-the-art pacers carry fat profit margins, that's a big plus for the bottom line."

o Articles published in medical journals and other publications have been critical of techniques used to sell pacemakers. We believe pacemaker sales practices have tended to increase the cost of such products:

--Several articles have alleged that sales practices by pacemaker sales representatives are corrupt and have caused high selling costs for pacemaker companies. They are said to aggressively pursue physicians to convince them to choose their brand of pacemaker.

--A 1981 economic research report (note) on the pacemaker industry commented that ". . . the primary marketing strategy of the newer entrants has been to increase the price of the pacemaker significantly, give the difference between the old and new price to the salesman, and attract salesmen, who have established relationships with physicians, from the older companies. As a result, the average compensation of a pacemaker salesman has more than doubled in the last five years and many of them are enjoying hefty six-figure incomes." The report stated there are roughly 500 to 550 salesmen for the 1,500 physicians that implant pacemakers. It also stated that "The absence of price competition as a significant factor in the domestic market has, of course, spawned the kind of competitive environment that exists today. The cardiologist or surgeon who makes the product decision is insensitive to price since the pacemaker . . . is reimbursable by various health insurance programs . . . ."

--A September 1, 1982 article in Medical World News reported that there have been charges of physicians being given free ski and gambling vacations, offered stock options at reduced prices, cash kickbacks, consulting jobs with duties not commensurate with liberal compensation, and lavish entertainment at conventions. The article also mentioned a lawsuit filed earlier this year by Medtronic against Intermedics charging that Intermedics offered and paid cash payoffs, gifts, and other things of value to doctors in expectation that they would prescribe Intermedics products.

Note: Source: Kidder, Peabody & Co., Inc. Cardiac Pacemaker Industry Analysis, January 22, 1981

--As another indicator of problems in this area: The FBI has begun an investigation of pacemaker marketing practices.

To the extent that these alleged unethical practices are true, Medicare ends up paying for such abusive practices through higher than necessary prices for pacemakers. Thus, if pacemakers bought for Medicare patients were bought through the use of contracts or other cost-limited arrangements, then the costs to Medicare of such unethical arrangements should diminish considerably.

There is yet another matter to consider. A recent report by the Public Citizen Health Research Group (an organization affiliated with consumer activist Ralph Nader) suggests that as many as 25,000 pacemakers are being implanted unnecessarily in Americans each year. The report concluded that over 75 percent of the (alleged) unnecessary implants were Medicare funded. While the Group's report does not draw this conclusion, one might assume that overly aggressive promotion efforts by pacemaker sales representatives could tend to sway professional judgement as to when pacemaker implants are necessary. In this regard, it is significant to note that the American Heart Association and the American College of Cardiology are convening a task force to write guidelines on when the need for a pacemaker is and is not indicated.

Savings of $64 Million May Be Possible

If Medicare paid the same amount for pacemakers as are offered by the Federal Supply Schedule we estimate that $64 million would have been saved by the Federal government in fiscal year 1982. Our savings estimate is shown below:

Pacemakers sold in the United States - Fiscal Year 1982 (estimated)	136,000
Estimated percentage of the U.S. pacemakers paid for with Medicare funds (we believe 80% is a conservative estimate)	x .80
Pacemakers bought by Medicare in Fiscal Year 1982 (estimated)	108,800
Average price paid by Medicare (based on our review of 2,804 pacemakers bought by 25 hospitals in 10 States)	$3,424
Total Medicare funds spent for pacemakers in fiscal year 1982 (estimated)	$372.5 million
Percentage savings available through schedule contract prices	x 17.26%
Medicare savings potential in fiscal year 1982 (estimated)	$ 64 million

Conclusion and Recommended Course of Action

The preceding brief discussion dealt with a number of considerations related to the whole question of Medicare payment for pacemakers: industry profits, unethical sales practices, the questionable necessity of some implants, and the more favorable prices available through GSA supply schedule contracts. Taken together, we believe these factors strongly suggest that Medicare may well be paying too much for these devices and that some sort of direct or indirect program payment limits are needed.

As is the case with renal dialysis services, Medicare is, by far, the major effective purchaser. As such, the effect of normal market forces has been subdued. Thus, we believe that the whole area of reimbursement for pacemakers is an area worthy of consideration quite apart from that of prosthetic devices or durable medical equipment.

We, therefore, recommend that the Administrator, HCFA, take action on this question with a goal of creating a mechanism whereby Medicare can limit its participation in the cost of pacemakers to reasonable and necessary amounts. Based on discussions with the Office of General Counsel, we believe that at least two general approaches to the problem are viable under present law:

o Prospective limits could be established on the amounts the Program would reimburse hospitals for the cost of these devices.

o HCFA could conduct experiments and demonstration projects (e.g., competitive procurement of pacemakers for Medicare beneficiaries; or reimburse the patient for these devices under Part B, subject to limits, waiving the deductibles and coinsurance).

* * * * * * * * *

If you or your staff wish to discuss the material contained in this draft report, please let me know or contact Philip Kropatkin, Acting Assistant Inspector General for Auditing. We would appreciate receiving comments on this draft report within 30 days of the date of this report.

APPENDIX

LIST OF HOSPITALS VISITED

ARIZONA
- St. Joseph's Hospital and Medical Center, Phoenix
- Walter O. Boswell Memorial Hospital, Phoenix
- Good Samaritan Hospital, Phoenix

CALIFORNIA
- Cedars - Sinai Medical Center, Los Angeles
- St. Joseph Medical Center, Burbank
- St. Mary Medical Center, Long Beach

COLORADO
- St. Anthony's Hospital, Denver
- St. Joseph's Hospital, Denver
- St. Luke's Hospital, Denver
- Memorial Hospital, Colorado Springs

FLORIDA
- Community Hospital, New Port Richey
- Mt. Sinai Medical Center, Miami Beach

GEORGIA
- Emory University Hospital, Atlanta

NORTH CAROLINA
- Duke University Hospital, Durham

NORTH DAKOTA
- Dakota Hospital, Fargo
- St. Luke's Hospital, Fargo

TENNESSEE
- St. Thomas Hospital, Nashville

TEXAS
- Baylor University Medical Center, Dallas
- Methodist Hospital, Dallas
- Harris Hospital, Fort Worth
- St. Luke's Episcopal Hospital, Houston
- Methodist Hospital, Houston

UTAH
- St. Mark's Hospital, Salt Lake City
- LDS Hospital, Salt Lake City
- McKay-Dee Hospital, Ogden

Appendix 3

MATERIAL SUBMITTED BY WITNESSES

ITEM 1. LETTER AND ENCLOSURE FROM WHITNEY A. McFARLIN, CORPORATE VICE PRESIDENT, PACING SYSTEMS GROUP, MEDTRONIC, INC., MINNEAPOLIS, MINN., TO SENATOR JOHN HEINZ, CHAIRMAN, U.S. SENATE SPECIAL COMMITTEE ON AGING, DATED OCTOBER 1, 1982

DEAR SENATOR HEINZ: Enclosed is the corrected version of my statement before the Senate Special Committee on Aging.

I am also enclosing a paper responding to the committee's report, which we would like included as part of the hearing record. The paper focuses both on the current problems identified in chapter 6 of the report and on the recommendations included in chapter 10. In our response we have tried to correct inaccuracies, to explain Medtronic's policies and practices where they differ from the industry practices you describe, and to comment on the need for and likely effects of the policy changes recommended.

If you have any questions about the material we are submitting, we would be happy to respond to further inquiries. Also, if we can be of help in any other way as you follow up on the committee's work, please let us know.

Sincerely,

WHITNEY A. MCFARLIN.

Enclosure.

RESPONSE TO INFORMATION PAPER OF THE SPECIAL COMMITTEE ON AGING ALLEGING FRAUD, WASTE, AND ABUSE IN THE MEDICARE PACEMAKER INDUSTRY, PREPARED BY MEDTRONIC, INC., OCTOBER 1, 1982

The committee's report identifies a number of alleged problem areas related to the manufacture, marketing, and use of cardiac pacemakers in the medicare program.

They include, in particular, the following issues: (1) Product performance and reporting requirements; (2) the cost to medicare of pacing therapy; (3) overuse and implantation procedure; (4) kickbacks and other illegal and improper inducements; (5) the frequency and cost of monitoring; and (6) the adequacy of pacemaker warranties.

In the discussion that follows each of these issues is addressed.

(1) PRODUCT PERFORMANCE AND REPORTING

(a) Reliability

The report alleges that "around 30 percent of all pacemaker operations in any given year involve replacement of the device." Medtronic's data on industry performance show a much different situation. In 1975, as the report properly indicates, replacements accounted for about 40 percent of total implants. Since then, however, the reliability and the longevity of pulse generators have been significantly improved. In 1982, the replacement market for the industry represented approximately 14 percent of total implants. For Medtronic, replacements are about 12 percent of total units.

The report further contends that despite the switch to lithium the "rate of explant appears to be the same." It notes that about 20 percent of patients die within the first year from unrelated causes and that the odds for the rest are that "the pacemaker will have to be replaced within 3½ years."

Medtronic's patient records show a significant difference in rate of explant between lithium and mercury-zinc pacemakers. They indicate that of more than 400,000 Medtronic pacemakers implanted since October 1973, less than 20 percent have been explanted within 3½ years. If only lithium powered pulse generators are

considered, the percentage of devices explanted within 3½ years drops to 4 percent. This compares with 45 percent of the nonlithium powered devices over a comparable 3½ year time period. Also, our records indicate that less than 10 percent of the patients die from all causes within the first 12 months after the implant.

(b) Electronic and Lead Malfunction

The report also discusses performance problems related to electronic and lead malfunctions, and it concludes that over one-half of pacemaker replacements are necessitated by malfunctions unrelated to the power source. Medtronic data do not support this conclusion. Our analysis of explanted devices shows that approximately 13 percent of returned Medtronic pacemakers have been removed because of reported lead or confirmed electronic malfunctions unrelated to the power source.

(c) Polyurethane Leads

The report asserts that the development of fissures in polyurethane leads raises a significant performance question. Performance data do not support this conclusion. Our experience over 4 years shows failure rates for polyurethane leads that are not statistically greater than those for silicone leads.

The development of surface cracks, in and of itself, is not cause for lead replacement. This phenomenon has been examined by polymer chemistry experts within Medtronic and by outside experts. All have concluded that the surface cracks are the result of the polymer relieving tension on the surface and that they are not a time-dependent function. As a result, we do not foresee significant performance problems with polyurethane leads, and we believe, as the report notes, that these leads offer substantial patient benefits.

(d) Reporting Practices

The report expresses concern about FDA's reliance on voluntary performance information supplied by manufacturers. Specifically, it alleges that manufacturers have proven reluctant to submit failure reports that might limit future sales or lead to some admission of liability. We cannot comment on the industry's performance. Medtronic, however, provides both the FDA and physicians accurate and timely information on product performance.

Medtronic recognizes the importance of and is strongly committed to the monitoring of device performance. The company maintains a registry that covers virtually all patients (95 percent) receiving Medtronic pacemakers, and the return of all explanted devices is encouraged.

The return and analysis of explanted pacemakers, which are encouraged under terms of our warranty, are an integral part of verifying possible product failures. Most devices returned to us are operating normally or have normal battery depletion. Whether or not the device is found to be operating normally, the results of our analysis are reported to the appropriate physician or to the hospital if the physician is not known. We also provide physicians with a product information report form to encourage the reporting of clinical experiences.

In addition, quarterly reports on patient status are given to implanting physicians, and quarterly reliability and performance reports on all devices are provided to advise physicians on the performance of a given model.

(e) Problems With Newer, Sophisticated Devices

In support of its claim that reliability and performance are continuing problems in the industry, the report alleges that one of Medtronic's new devices is "fundamentally flawed" and that it could "result in a variable reverse flow of blood from lower to upper chambers." These statements are not accurate.

We assume the report is referring to a potential problem involving one mode of operation of the Versatrax, Medtronic's newest pacemaker. A complication may occur when the Versatrax is programed to operate in one of its dual chamber modes if the patient has slow "retrograde conduction." Retrograde conduction involves the reverse electrical flow of the cardiac conduction activity from the lower to upper chambers—not the reverse flow of blood. When such a condition is present and is relatively slow, the Versatrax pacemaker rate can increase to a higher rate than programed. This possibility, which is a potential complication in all manufacturers' devices of this type undergoing clinical evaluation, is described in the product labeling.

Consequently, for some patients the Versatrax pacemaker can only be used in one of its two dual chamber modes. This limitation in no way represents a fundamental flaw in the product.

The Versatrax has been the subject of over 1½ years of clinical study. It is currently completing its clinical trials within the United States and has been marketed outside the United States since January 1982. The FDA's Circulatory System Devices Advisory Panel recommended approval of Medtronic's application to market the pacemaker in May 1982. We expect final FDA approval soon.

(2) COST OF PACING

(a) Total Cost to Medicare

Throughout the report concern is expressed about the cost to medicare of pacemaker implants and followup activities. The report estimates that medicare's share of the total cost of pacemaker therapy will exceed $2 billion in 1982, representing 80 to 90 percent of the cost of all pacemaker procedures.

Medtronic's experience confirms that medicare is responsible for a majority of the pacemaker therapy bill. Our figures suggest, however, that its share of the total cost may not be as large as is stated in the report.

Medicare accounts for 58 percent of Medtronic's revenues from domestic pacing products and services. Other Government programs account for another 17 percent of these revenues, and private payers account for the remaining 25 percent. Patients who have received Medtronic pacemakers range in age from an 18-hour-old infant to a person 120 years of age. About 60 percent of all patients are between the ages of 60 and 80.

(b) Industry Size

Our data on the size of the industry also differ from those contained in the report. Our estimate of the number of implants that will be done in 1983 is 123,000, nearly 20 percent less than the committee's estimate.

(c) Pacemaker Prices

With regard to the cost and pricing of pacemakers, the report states that pacemakers cost $600 to $900 to manufacture and are billed to hospitals at $2,000 to $5,000. These figures are basically correct.

Medtronic's pacemakers range in price from $1,495 to $4,695. In constant dollars, the average price of the company's pacemakers has increased less than 5 percent per year over the last 12 years, and the increase in real prices can be attributed to the significant improvements in product performance, reliability and longevity that have occurred over that period. As a result, although the price of a pacemaker has increased, the cost of pacing per patient per year has dropped significantly.

One can argue as to whether or not current prices are appropriate. Comparisons to the international market, such as those contained in the committee report, however, can be misleading. The international market in general has a substantially larger portion devoted to simple ventricular pacing than the United States has. If similar products are compared, prices for pacemakers in the United States are found to be higher than prices in many countries, but not all. Currently, the average price for pacemakers in Japan is approximately 30 percent higher than in the United States. Prices in Switzerland are about the same as here or a little higher. The price in France is about 15 percent less than in the United States, and in the United Kingdom, pacemakers sell at prices about one-half that in the United States.

In several of these countries, government-established prices and the participation in the marketplace of government-subsidized domestic producers distort the pricing pattern. Were Medtronic to sell all of its pacemakers at these lower levels, the company would not have an adequate financial return to support continued investment in the business. Research and development funding would decline and product improvements would stagnate.

(d) Medtronic Cost and Profitability

On the issue of cost, the committee's figures are correct if one uses a narrow definition of cost, i.e., only direct manufacturing cost. It is misleading, however, to focus on the difference between manufacturing cost and selling price as a measure of profitability.

Additional expenses that are not a part of the manufacturing cost include the costs for research, product development, quality control, complying with regulatory

requirements, warranty expenses, accounting and other overhead, marketing, sales and distribution. After taxes are paid, the remaining profit must cover the costs of capital and dividends, and provide funds for future growth.

The report acknowledges some of these costs but alleges that the "principal difference between product cost and sales price consists of marketing and profit." It goes on to refer to one firm that dedicated nearly 50 cents of every sales dollar to marketing activities with half of that total—20 to 30 percent—paid as sales commission.

Medtronic's cost structure is substantially different. Marketing and sales costs represent approximately 16 percent of Medtronic's U.S. revenues, of which sales commissions are 3 percent. This means that the maximum commission on a pacemaker and lead sale for a Medtronic sales representative is about $150. In addition, sales personnel are paid a base salary of $30,000 to $40,000.

In general, Medtronic's level of profitability and its cost structure are very similar to those for computer manufacturers and manufacturers of other high technology products. Research and development costs are high—8 to 9 percent for Medtronic currently. General and administrative expenses also are high, in part because of the regulatory burden the company faces and its strong emphasis on product testing and quality control. Net margins (pretax) for the company are approximately 20 percent.

(Contrary to what is stated in the committee report, Medtronic's earnings are not in excess of $335 million. That figure represents total sales for 1982. The company's earnings in the same year were $47 million.)

(e) Hospital Pricing

The committee's concern about pricing extends beyond the rule of the manufacturer to that of the hospital. Although the report's discussion of hospital pricing does not relate directly to Medtronic, the issue that is raised deserves comment.

The report notes that hospitals increase by 50 to 150 percent the cost of the pacemaker and "pass the total on to medicare." This statement is misleading.

We understand that hospitals differ greatly in how they price pacemakers. Some do impose significant markups; others do not. So it is important to note that hospitals are reimbursed under part A of medicare on the basis of the costs they incur, not the charges they impose. While pacemakers may be billed to medicare at charges substantially above the cost to the hospital for the pacemaker, all medicare charges including those for pacemakers are subject to an annual audit based on the hospitals' actual costs. The extent to which a hospital marks up its pacemakers may influence its ratio of medicare charges to total charges and as a result may have an impact on medicare's share of total costs, but reimbursement ultimately will be cost based.

(f) Pacemaker Reuse

Related to the issue of cost in the committee's report is the question of reuse of pacemakers. Medtronic recommends against the reuse of implanted pacemakers. It has disclaimed in its warranties responsibility and liability to everyone except the initial user. This policy is based upon reservations about the safety, reliability, and performance of refurbished pacemakers. Meeting likely FDA requirements on safety and efficacy would be difficult and not likely cost-effective.

While pacemakers certainly can be resterilized and reused and are in certain other countries, there are several issues that would have to be addressed were this to become common practice in the United States. They include:

(1) Permission would have to be obtained from the previous user (or the representatives of his/her estate or next of kin) to explant the device and transfer ownership of the device back to the hospital or other institution that would refurbish it.

(2) An informed consent would have to be obtained from the patient in whom the pacemaker would be reimplanted, disclosing that it is a used device.

(3) Product reliability would have to be assured in the explantation, handling, storage, cleaning, and resterilization of the device. Qualification of ETO sterilization would be difficult because of the unknown bioburden on the explanted device. Even if good manufacturing practices were established and proper records kept, the pulse generator might well be subject to conditions that would compromise its reliability.

(4) Finally, responsibility for the safety and effectiveness of the device would have to be clearly assigned to the institution or practitioner resterilizing or reusing it.

(3) IMPLANTATION PROCEDURES AND OVERUSE

The report expresses concern about both the number of pacemakers being implanted in the United States and the professional qualifications of persons involved with the implant procedure.

(a) Overuse

On the issue of overuse, we would offer the following observations in response to the committee's concerns:

(1) Decisions on the appropriate utilization of pacemakers are being resolved, as they must be, by the medical profession. The attending physician must ultimately take responsibility for the decision to prescribe or not prescribe a pacemaker.

(2) Applications for pacemaker therapy have been significantly expanded in recent years because medical research and clinical practice have shown new patient benefits from pacing. Increased applications also reflect the reduced risks to patients of pacemaker implants. The initial implant requires less complicated surgery now than before, and is now usually performed under local anesthesia. Also, with programability, pacemakers can be noninvasively controlled to handle most complications and changing patient cardiac function.

(3) Medtronic legitimately shares with the medical community an interest in learning more about the appropriate applications of pacemaker therapy. Consequently, the company supports medical research and educational programs that are designed to test the merits of and identify the appropriate indications for use of its pacemakers. The company encourages physicians to publish their findings in peer review journals; it sponsors medical seminars and scientific exhibits, and it disseminates resulting information through a quarterly pacing journal.

(4) The studies which conclude that a significant number of pacemaker implants are unnecessary are themselves the subject of much criticism, as was noted in Dr. Seymour Furman's letter of August 30, 1982, to the committee and in his testimony at the hearing. In one study cited in the report, results may have been skewed because more "controversial" patients were subsequently referred to other institutions after peer review was instituted at the hospital under study. In the other case, the reliance on final discharge diagnosis as the basis for evaluating the appropriateness of the prescription has raised concerns about the adequacy of the data.

(5) A comparison of the usage rate in the United States with those in other countries says little about the appropriate level of usage unless consideration is also given to the adequacy of the care provided. It could equally be argued that pacemakers are under-prescribed outside the United States.

Also, contrary to what is stated in the report, the United States does not implant more pacemakers per capita than any other country in the world. In 1980, the number of initial implants per 1 million patients was greater in West Germany than in the United States. At that time, the Federal Republic of Germany implanted 439 units per million versus 414 per million in the United States. The level in France was 313, and the average for all of Western Europe was 230 units per million.

(b) Physician Reliance on Sales Representatives

Related to the issue of overuse is the concern expressed in the report about the "undue reliance" by the physician on the pacemaker salesman, specifically the use of sales representatives in the operating room.

Medtronic's sales representatives may be present in the operating room if requested to be there by the physician. Their primary role is to answer any questions the physician may have concerning the operation of Medtronic equipment and to provide requested technical support. They do not scrub, are not in the sterile field, do not directly participate in the implant or followup procedures and do not render any medical decisions.

Some physicians do not request the representative to be present unless they are faced with a very difficult case that requires extra "troubleshooting" or additional equipment. Other physicians request a representative to attend in each case. Because of this variable demand for service, Medtronic sales and technical representatives are trained to provide assistance to the physician upon request.

Contrary to what is suggested by comments in the report, sales representatives—at least those at Medtronic—do receive extensive training both in the classroom and in the field.

In preparation for their duties, sales representatives receive instruction in the anatomy and physiology of the cardiovascular system, electrophysiology, electrocar-

diology, basic electricity, cardiac hemodynamics, indications for pacing, conduction disturbances, cardiac pharmacology, and basic pacing. After completion of their study in these subjects and preliminary field experience, they complete an intensive 2-week course covering power sources, functional areas of an implantable pulse generator, electrical sensing and stimulation, EKG recognition and analysis, troubleshooting and the use of the pacing systems analyzer. All sales representatives, in addition, receive ongoing training and education through seminars, sales meetings, and written materials provided by the company.

The training of other technical representatives at Medtronic is even more extensive than that described for sales representatives.

(4) KICKBACKS AND OTHER ILLEGAL AND IMPROPER INDUCEMENTS

(a) Medtronic's 8-K

Included in the report's discussion of improper inducements is a summary of the 8-K that Medtronic filed with the Securities and Exchange Commission, March 8, 1977. The summary is misleading in several aspects. The report makes the statement "no improper domestic activities were identified or disclosed," leaving the impression that domestic activities were not investigated. This is not true. The 8-K recites the extensive investigation of both foreign and U.S. business practices, the results of which disclosed no evidence of "any bribes, kickbacks, or other such improper payments in the United States."

Under the discussion of "specific bribes to physicians," the committee report also makes the statement "payments to hospitals totaled $554,600 in a 3-year period." Under this heading and in this context, the statement is clearly misleading. As the 8-K explains, it was a customary practice of Medtronic and other companies in the industry to make donations of medical equipment to hospitals and clinics in one foreign country. The total value of these donations over a 3½-year period was $554,600. None of these were kickbacks to physicians. The practice was discussed in the 8-K because "the legality of this practice is unclear in the country where it occurred." Therefore, the practice was discontinued in order to review and evaluate it.

Reference is made in the committee's report to the adoption of a written business code. It should also be noted that as an additional step to insure compliance with the code, Medtronic requires of all key employees an annual certification of compliance.

(b) Improper Inducements

More generally, with respect to the allegations regarding improper inducements, Medtronic's policy is clear. As we stated in our testimony, it is our policy not to engage in such illegal activities, and we have been diligent in our efforts to insure that employee practices conform to company policy.

In regard to the specific areas of concern identified in the report, we would offer the following additional comments.

1. Liberal payments of "unreimbursed medical expenses"

For any pacemaker replaced by a Medtronic device, Medtronic will cover reasonable, unreimbursed medical expenses. In the past 2 years, claims paid by the company on more than 2,800 cases have averaged $275 each. No claims are paid without adequate documentation indicating the charges and what was covered by third-party payers. If the implanting physician and others involved in the operation are paid directly, the patient receives a notification that such payments have been made.

The purpose and reason for agreeing to pay or to contribute to the payment of, such unreimbursed medical expenses was set forth initially in Medtronic's XYTRON patient management option, which provided:

"We are aware that some physicians have XYTRON patients for whom they have not been able to reach a comfortable patient management decision.

"We have been informed that there are instances in which a physician may conclude that it would be in a patient's best interest to replace a XYTRON, but are concerned about the cost of this replacement being borne by the patient.

"To allow you to exercise medical judgment without worry for the patient's financial situation, should you at any time conclude that the patient's medical interest is best served by replacing the XYTRON with any other Medtronic pulse generator, we will pay the patient up to $450 of uninsured medical expenses incurred in the replacement procedure."

The XYTRON patient management option was reviewed by HCFA in early 1979. In a letter to Medtronic's president in April of that year, the HCFA officials opined that "We (HCFA) do not believe that the effect of the patient management option is such as to bring it within 42 U.S.C. section 1395 nn as an inducement to 'purchase * * * or recommend purchasing * * * or ordering any goods, facility, service of item * * *.'"

Although Medtronic has now expanded its offer via its warranties to pay reasonable unreimbursed medical expenses for replacement of units other than XYTRON, the rationale for so doing remains the same.

2. Kickbacks disguised as payments for "clinical evaluations"

Properly conducted and controlled clinical trials are essential to good business practice. Medtronic conducts clinical studies on new pacemakers to meet both internal and FDA requirements for establishing device safety and efficacy. Clinical studies are also used to collect data on which performance claims and labeling statements can be based, to establish appropriate instructions for device use, and to develop requirements for product training programs.

To insure proper compensation and to facilitate compliance with the protocols of the clinical evaluation, Medtronic has a policy on "institutional compensation for clinical investigations." The policy provides for payments to hospitals or other institutions of a nonnegotiable amount that varies between $150 and $250 for each patient evaluated as part of a formal study. The specific amount depends on how much data is required by the clinical protocol at the time of the implant, and the extent and frequency of the additional data required from multiple followup visits.

The payments are not intended, as the committee's report alleges, to buy the allegiance of pacemaker professionals. Rather, they are designed to defray the costs of additional patient testing and the time of nurses and technicians required in preparing and submitting clinical data to the company. The total amount spent by Medtronic for this purpose in fiscal 1982 was $18,096.

In addition to clinical pacemaker studies, Medtronic also sponsors several basic clinical pacing research projects with a limited number of physicians. In these cases Medtronic covers the expenses of the hospital, institution or physician as identified in the protocol.

3. Use of "free goods" as an inducement to do business

The report is critical of the practice of providing business equipment as so-called "free goods." Its concern is that "gifts" of pacemaker accessories represent an improper inducement to do business.

The discussion in the report is misleading in several respects, at least as it pertains to Medtronic's situation.

Medtronic has corporate policies that generally prohibit the giving or accepting of gifts and gratuities (exceptions include promotional materials, training materials and items of insignificant value). Medtronic also has specific corporate policies that regulate the provision of "no-charge merchandise." Those policies make clear that support equipment provided at no charge is not to be used to provide personal benefit to physicians or hospital personnel.

In 1978, Medtronic specifically requested an advisory opinion from the FTC with regard to the appropriateness of providing "free goods." A limited program of providing no-charge support equipment was initiated when the agency declined to respond and intense competitive pressures required action on our part.

Medtronic provides pacing system analyzers to hospitals or clinics that purchase our pacemakers. Receivers are provided at no charge to hospital accounts for use by their staff physicians. In the case of programers, Medtronic provides the equipment to hospitals but retains ownership. The company is responsible for the repair, updating and servicing of this equipment. Medtronic also maintains the equipment on its property records and takes investment tax credits as appropriate.

Transmitters are provided to patients on request of their physician and become the property of the patient.

4. Offers of training

The report alleges that offers of training are freely provided as an inducement to do business. The discussion in the report implies that training practices are improper. Medtronic disagrees. Training of the physician in the use of our equipment is an important part of our responsibility. In addition to the training we do ourselves, we provide a forum for physicians who are experts in both the indications and the use of pacing to instruct their colleagues. Some of the courses that have been offered under Medtronic's supervision are approved for continuing education credits by the American College of Cardiology.

5. Travel, entertainment, and so-called "fringe benefits"

The use of travel and entertainment as an inducement to do business is a primary concern expressed in the report. Medtronic's policy with respect to these activities is to reimburse employees for reasonable and necessary expenses incurred in the pursuit of business. The company's expenses in these areas are within the parameters of what would be considered "ordinary and necessary." Sales representatives are employees of the company, and their expenses must be detailed and adequately documented for review and approval by appropriate management personnel. They are also subject to internal audit. The company's travel and entertainment expenses have passed IRS audit through 1980.

With respect to the specific question of physician travel, Medtronic's policy is that travel for physicians or their staff will be provided for visits to Medtronic manufacturing locations and for the purpose of education. While certain of these educational opportunities may take place at nonmanufacturing locations, the principal purpose of the trips must be educational, as is demonstrated by the meeting schedules.

(5) THE FREQUENCY AND COST OF MONITORING

The report concludes that the frequency schedule for followup monitoring of pacemakers appears "excessive" and that payment levels "appear outrageous."

(a) Frequency

Medicare guidelines covering the frequency of pacemaker monitoring have recently been revised. New procedure codes, which take into account the differences in performance between mercury-zinc devices and lithium-powered pacemakers, went into effect in October 1980. The new schedule reduces the frequency for lithium pacemakers based on the input of physicians expert in pacing therapy.

(b) Rates

On the question of payment levels, it should be noted that the current schedules take into account not only the variable costs of monitoring and providing evaluation, but also an allowance for the cost of equipment needed to conduct such followup.

If the cost of equipment is considered along with the variable costs, payment rates are not excessive. Medtronic has a free-standing business, Cardiocare, that provides a 24-hour service for pacemaker monitoring. This service is run and managed by a staff of trained professionals and currently follows approximately 15,000 patients. The very large majority of these patients are covered by medicare, yet Cardiocare's pretax return on sales is less than 10 percent.

To the extent that the institution or individual is provided such equipment on a "free basis" as a result of pacemaker purchases under medicare, it may be appropriate to develop an alternate fee schedule.

(6) ADEQUACY OF PACEMAKER WARRANTIES

The report focuses on several issues related to the adequacy of warranties.

(a) Extent To Which Warranties Are Honored

One concern is whether, and the extent to which, credits are issued under the terms of the warranty. The report alleges that "pacemaker warranties are more honored in the breach than in the observance."

This conclusion is inaccurate as applied to Medtronic. Medtronic provides a credit on any purchased Medtronic pulse generator if:

It is implanted prior to its "use before date."

It is found or determined to be "out of specification" (i.e., if it fails to function within expected tolerances of performance); and

It is replaced with another Medtronic unit.

The terms and amount of this credit are set forth in the warranty, which accompanies the unit.

Furthermore, any unit that qualifies for credit under Medtronic's warranty is given that credit whether or not the claim is made. We believe our practice in this respect is unique within the pacemaker industry. A recently conducted survey showed that over 90 percent of all warranty credits issued by Medtronic are issued in situations where no claim or demand for credit for the unit has been made.

(b) Determination of Device Performance

The report also expresses concern that "performance of the devices and, therefore, validity of warranty is exclusively determined by the manufacturer." Again, the facts in Medtronic's case are different. The determination of whether Medtronic unit is "out of specification" is based upon physical analysis of that unit, clinical information, and other data. The analysis of the unit is typically but not always conducted by Medtronic. Over 100 Medtronic units per year qualify for credit based upon clinical information (e.g., an EKG) showing that the unit operated "out of specification" in the clinical setting even though it was found to be functioning properly when analyzed by Medtronic. The involved physician is sent a letter on each returned Medtronic unit reporting the results of the analysis.

Medtronic issues the credit for the unit to the unit purchaser, i.e., typically a hospital. We are also instituting a practice of advising both the physician and the patient, as well as the hospital, when and to whom the credit has been or will be issued.

The report cites a warranty complaint against Medtronic made by Willie A. Meadows, who received a Medtronic pacemaker in February 1977, that was subsequently explanted in December 1977, and replaced with another Medtronic unit. Mr. Meadows' explanted pacemaker was returned to Medtronic for credit under warranty. Upon analysis by us, it was found to be functioning normally. Thus, no credit was given.

Of concern to the FTC, as noted in the report, were the terms of the warranty providing that Medtronic would have the exclusive right to analyze a unit returned for credit. These terms were changed in March 1977. Also, as noted above, units shown to be operating "out of specification" in the clinical setting qualify for credit even though they are found to be functioning properly when analyzed by Medtronic. In Meadows' case, however, there was no clinical evidence of failure of the pacemaker. In fact, the physician's report submitted to Medtronic on the returned unit indicated that the pacemaker was explanted for reason other than malfunction of the pulse generator.

(c) Extent of the Warranty

Also at issue in the report is the extent of the warranty offered. The report implies that manufacturers have abused the medicare system by reimbursing only for uninsured medical expenses, thereby inappropriately subordinating their responsibility for product liability to medicare. This conclusion is not supported by the facts. Over the years the pacemaker industry has increased warranty coverage as improvements in pacemaker longevity have been made. In 1971, the standard industry warranty provided full replacement credit for up to 12 months with a declining credit up to 36 months. No provision was made for uninsured medical expenses.

In 1978, Medtronic introduced its "pacing for life" limited warranty, which provided patients with full replacement credit for pulse generators that failed to function properly for any reason. The new limited warranty further provided reimbursement for uninsured medical expenses for units which failed to function due to a defect in the device. Warranties of this type are now common in the industry.

Furthermore, under current policy medicare does not have a right of subrogation with respect to pacemakers. Historically, medicare has been the primary payer for hospital and medical services even in cases where a beneficiary's need for services was related to an injury or illness where third parties were liable. In fact, beneficiaries who have been able to collect damages from negligent third parties have been under no obligation to turn the proceeds over to medicare. Our understanding is that medicare's policy with respect to subrogation has been prompted by concern over the difficulties in ascertaining private insurance liability and the attendant delays in payment.

(d) Impact of Warranty Coverage on Replacements

The committee report expresses concern about the impact of warranty coverage on the physician's decision to replace a pacemaker. In so doing, it focuses specifically on the Medtronic recall of the XYTRON. Implicit in the report's discussion is the contention that Medtronic gained from the recall. This is not true.

As noted earlier, Medtronic's willingness to cover unreimbursed medical expenses permitted physicians to exercise appropriate medical judgment without concern for the patient's economic well being. Medical expenses reimbursed by Medtronic in connection with XYTRON replacements averaged $270. Furthermore, taking into account the uninsured medical payments and the cost of the replacement product

provided under the warranty, Medtronic did not profit when a physician elected to remove a recalled XYTRON I and replace it with either a XYTRON II or a XYREL.

The final chapter of the report outlines several policy changes for consideration by the Congress, the Department of Health and Human Services and the Food and Drug Administration. In the final pages of this response, we comment briefly on the need for and likely effects of the policy changes recommended. Our intent is not to provide a comprehensive analysis of each recommendation, but rather to share some general concerns and to introduce another perspective into the policy discussions that will occur over the next several months.

1. Establish an alternative purchase mechanism for pacemakers; explore the use of contract purchasing and negotiated rates

Medtronic shares the committee's concerns about rising health care costs and agrees that increased price sensitivity on the part of the purchaser is desirable. We are not persuaded, however, of the merits of devising an alternative purchase mechanism specifically for pacemakers.

First, we are concerned that a system of contract purchasing or negotiated rates would subordinate quality, reliability and performance considerations to price. There are substantial and discernible differences among competing products in the marketplace today. Pacemakers are not generic. They differ in features, reliability, quality and service availability. Current statistical data, for example, show Medtronic units to be anywhere from three to six times more reliable than competitors' products. Features such as size, weight, programability and telemetry also distinguish products. Any purchasing mechanism should maintain flexibility for the physician to take into account these performance differences in responding to varying patient needs.

Second, we believe that only through innovation can the industry continue to improve both the cost-effectiveness of pacing and the quality of patient care. Our concern is that with the changes proposed prices over time would move to unreasonably low levels, destroying the incentives for continued research, investment and product innovation. With the Government in a position to exert substantial market power, the normal interplay between supply and demand would not exist.

Third, the alternatives proposed would focus pricing decisions inappropriately on the cost of the initial implant rather than the total cost of providing pacing therapy.

2. Establish a pacemaker registry

Medtronic recognizes the importance and value of monitoring device performance, and we believe a pacemaker registry is useful in tracking such performance. We are concerned, however, that the costs of implementing a national, Government system may not be justified.

As noted earlier, product reliability has improved significantly since 1974 when the FDA initiated its registry. The committee's report states that in the 6 years of its existence, 4 percent of the pacemakers in the registry were reported to have failed in a catastrophic or potentially life threatening way. In contrast, data on Medtronic's lithium-powered devices, which have been sold since November 1975, show a catastrophic failure rate of less than 0.09 percent.

Also, Medtronic already maintains a registry, and we assume other responsible manufacturers do as well. Therefore, we would encourage the FDA to work with the industry to take advantage of work already being done in this area. Even if a national registry were established, Medtronic would not relinquish its responsibility for monitoring and analyzing devices.

As an alternative to a national registry, we would suggest that each manufacturer be required by the FDA to establish a registry covering its products. The FDA could establish standards and procedures for implementing such registries, which would be open to periodic audit by the FDA. Regular reporting of results could be required to ensure that adequate data were available to physicians and to the FDA.

3. Require the establishment of a performance bond for pacemaker firms to insure collection of warranties

Medtronic agrees that patients' rights to collect on pacemaker warranties should be adequately protected. We have provided for such assurance by establishing reserves covering our warranties.

We are not in a position to evaluate whether there is a problem on warranty collection related to company failures. If a judgment is made that performance bonds or some comparable protection mechanism are needed, we would not object. Such a requirement, however, would add to the cost of the pacemaker.

4. Study proper pacemaker indices and develop pacemaker utilization screens

Medtronic has encouraged clinical studies and research aimed at clarifying the benefits and risks to patients of pacing therapy. We believe that continued research directed at the safety, efficacy, and cost-effectiveness of pacing is needed. Ultimately, the medical community has the responsibility for determining appropriate indications for pacing and developing guidelines to govern use. Such work is being undertaken under auspices of the ICHD (Inter Society Commission on Heart Disease).

The need for a system of peer review or a requirement for a second medical opinion should be considered. We would be concerned, however, if rigid utilization screens were adopted that did not provide adequate flexibility for the physicians to exercise judgment in determining whether or not a pacemaker is needed and, if so, what type.

5. Review and reduce physician payment screens

We are not in a position to evaluate the appropriateness of current fee levels. In general, however, we believe fees should be tied both to the skill and the effort required of the physician.

6. Review and reduce medicare transtelephonic monitoring schedules and payment levels

Monitoring frequency schedules have been reviewed and adjusted based on changing product capabilities and physician input regarding patient need. Such review should continue to take place periodically.

Regarding the fee schedule, consideration should be given to the appropriateness and feasibility of differentiating between providers who purchase their equipment and those who do not.

7. Establish a system of centralized service for pacemakers where specific expertise can be developed and a minimum level of use maintained

Implicit in this recommendation is a call for physician certification. Medtronic believes this is an issue that must be dealt with by the medical community. There is a growing concern among a few medical pacing experts that the sophistication of pacing has overtaken the capacity of some medical practitioners. This may be so. Pacing is a very small part of some physicians' practice. There is unquestionably an expanding need for training of cardiologists, surgeons, nurses and technical support people in the basics of pacing as well as in the proper utilization of pacemakers with expanded capabilities. An adequate skill level is essential, but the number of implants may not be the most meaningful measure of competence. Finally, the goal of increased expertise should *not* be maintaining a "minimum level of use," but rather insuring that pacemakers are used in a cost-effective manner to provide the best level of care possible.

8. The report includes three recommendations related to warranties

(a) Establishment of a payment edit by intermediaries to assure proper warranty credits.

(b) Prohibition of the return of explanted devices to manufacturers; and

(c) Prohibition of warranties conditioned on replacement by the same company.

Medtronic's practice is that any unit which qualifies for credit under its warranty is given that credit whether or not a claim for it is made. As noted earlier, over 90 percent of all warranty credits issued by Medtronic are issued in situations in which no claim or demand for credit for the unit has been made. Consequently, we would agree that some system should be established to assure proper payment.

Medtronic would strongly object to a prohibition of the return of explanted devices to the manufacturer. Also, we would be concerned if explanted devices were diverted to other laboratories resulting in delayed information to the manufacturer.

Analysis of explanted product is essential to the company's efforts to improve safety, reliability, and product performance. Without it, we would be unable to recognize and correct product problems. Our experience with analyses conducted outside the company is that the expertise required to conduct an accurate and complete analysis is generally not available. Without knowledge of how the product is designed, analysis is extremely difficult, and such design information is necessarily proprietary.

We would recommend as an alternative that companies be required to report periodically on product performance and that FDA establish by regulation a system for inspecting records on returned units and for evaluating analysis procedures. This would minimize cost and improve results.

A prohibition of warranties conditioned on replacement by the same company would run counter to basic contract law.

11-485 O - 83 - 11

9. Mandatory reporting requirements for product failures should be established by the FDA

The Medical Device Amendments of 1976 provide authority for FDA to require reporting of adverse experiences to assure device safety and effectiveness. In view of mechanisms already available to the FDA (for example, PMA post market approval reporting requirements, USP device defect reporting system, etc.), we question the need for an MER regulation covering all medical devices. If a separate regulation is to be issued, however, it should be limited to device-related deaths and serious injuries. Our trade association, HIMA, is currently working with FDA on this issue.

10. Insure the propriety of clinical testing procedures

FDA already has the authority to insure the propriety of clinical testing procedures and is actively involved in reviewing the effectiveness and appropriateness of clinical studies conducted by companies. Medtronic agrees that payments on clinical testing should be commensurate with the services provided. FDA, however, is not charged with responsibility for controlling such payments.

11. Develop procedures for the proper evaluation of devices explanted from medicare beneficiaries

As discussed in No. 9 above, Medtronic has in place effective procedures for evaluating explanted pacemakers. We believe FDA's role in this area should be to establish appropriate protocols and to review manufacturers' procedures and results.

12. The VA should renegotiate its purchase contracts to obtain greater savings

The mandated discounts already obtained by the Veterans Administration are significant, and current VA contract provisions, which include a mandatory disclosure of all supplier discounts to third parties, enable the agency to negotiate the best prices available.

It is unlikely that companies will be willing or able to sell to the VA at prices much lower than those already offered. Most companies look at the VA business as marginal, incremental business. As such, they have been willing to accommodate a lower rate of return. Unless greater economies can be associated with the large volume purchases of the VA, it is unlikely that further discounts can be offered.

ITEM 2. INTERMEDICS, INC., FREEPORT, TEX., RESPONSE TO U.S. SENATE SPECIAL COMMITTEE ON AGING STUDY (INFORMATION PAPER) ON FRAUD, WASTE, AND ABUSE IN THE MEDICARE PACEMAKER INDUSTRY, DATED OCTOBER 21, 1982

I. Overview

The purpose of this report prepared by Intermedics, Inc., is twofold: To assist the U.S. Senate Special Committee on Aging in its study of the pacemaker industry and possible revision of medicare reimbursement programs; and to correct for the committee's hearing record the many statements in the committee staff's information paper (the "paper") that are either untrue or profoundly inaccurate. As the committee's impressive series of hearings on health care and the medicare/medicaid program indicate, problems pervade Federal and State cost reimbursement plans for many health care programs—not just pacemaker therapy. Therefore, it is hoped that the committee will seek evidence from all health sectors for its future deliberations, and not rely solely on information papers that are prepared without input from the principals in companies whose policies and practices are discussed. Intermedics' concern is that while the staff's paper is described as an effort to expose overall weaknesses in the medicare reimbursement program, it is much more. It approaches an indictment of medical device manufacturers, and, specifically Intermedics.

When allegations are as broad and questionably substantiated as those in the paper, they taint the professional reputations of all those implicated, whether guilty or innocent. The paper's discussion of wrongdoing involves generally allegedly improper sales and marketing practices, entertainment and other inducements to physicians to purchase specific devices, excessive profits earned by manufacturers, and illegal transfers of corporate stock to physicians. The paper attacks the contributing role of physicians in alleged excessive and unwarranted pacemaker implants, and the role of private hospitals in huge markups of the cost of pacemakers after their acquisition from the manufacturer.

Intermedics welcomes the opportunity to supplement the committee's record first with a more thorough factual description of pacemaker technology, its success and

acceptance in the medical community, and Intermedics' expenditures for making sophisticated, high-quality pacemakers available to the consuming public. Second, the report discusses the staff paper's inaccurate allegations of fraud, waste, and abuse as they relate to Intermedics. The many allegations in the paper directed at other parties will not be addressed.

The management of Intermedics believes it is crucial to provide this response for several reasons. First, it is important to give some factual context to the committee's study and dispel the serious misimpressions that have resulted in a $200 million loss in Intermedics stock value. Also unfortunate has been the effect on patients who, although they genuinely require pacers, are leaving hospitals without necessary implants out of fear about pacemakers' reliability and questions about the integrity of physicians and hospitals. Second, Intermedics wishes to emphasize its dedication both to continued research and development in sophisticated pacemaker technology, and to the proper training and conduct of all company personnel and sales representatives so as to prevent future abuses and ensure pacemaker patients the treatment they need to enjoy healthy, productive lives.

II. Pacemaker Technology

A major concern Intermedics has with the staff's paper is that, while it purports to offer a balanced view of pacemaker therapy, it only cites authorities critical of extensive pacemaker utilization. The paper hardly provides the Senate Aging Committee, the full Senate, and the public a fair understanding of the remarkable advancements pacemakers have made in heart patient therapy and longevity, particularly in the last decade.

A. Pacemakers' contribution to cardiac health improvements

While the paper acknowledges (see page 50) that pacemaker implants have been used successfully for certain forms of heart disease (complete and partial heart block, Stokes Adams' syndrome, sick sinus syndrome, etc.), the balance of the paper reports only those authorities who have criticized widespread use of pacemaker therapy. Moreover, the importance and popularity of pacemakers was improperly downplayed by the paper's statement that if the 500,000 implanted pacemakers stopped functioning, only 10 percent of pacemaker users would experience significant complications, including death for 1 to 5 percent of those users, and the remaining pacemaker patients would only notice "a difference" in their quality of life (see page 10). Not only is the staff's reporting callous, it tremendously understates the impact of pacemakers on the lives of present and future heart patients.

From the statistics that Intermedics has been able to collect on the subject, pacemakers' contribution to health improvement has been far more substantial. Approximately 146,000 people in the United States will receive an implanted pacemaker in 1982. Many of these people, particularly those who suffer from Stokes-Adams attacks or classic heart block, will be able to function normally again as useful citizens. The effectiveness of pacemakers in restoring health to patients is well documented in the medical literature. The committee's attention is directed specifically to the sources numbered 1, 6, 8, 49, 52, 62, 68, and 90 in the bibliography [1] attached at the end of this report.

Pacemakers now are used to control various tachyarrhythmias. In many cases, they do a better job than cardiac drugs, without the drugs' debilitating side effects. As a matter of fact, when pacemakers are used along with drug therapy, they can control certain arrhythmias better than drugs alone. Studies that support this conclusion are numbered 2, 3, 5, 7, 11, 14, 22, 51, 69, 70, 83 and 88 in the attached bibliography.[1]

B. Product differences and capabilities

Also inadequately addressed in the staff's paper are the substantial variations among the pacemaker products on the market. The paper notes in essence that there are no significant differences among the cardiac pacemakers manufactured by the leading companies (see page 22). Another overgeneralization in the paper is that the costs to manufacture pacemakers range from $600 to $900, and that the price paid by the hospitals range from $3,000 to $5,000 (see page 30). These generalizations fail to take into account other costs that affect the price of pacemakers (such as research and development, Federal regulatory compliance and other costs). They

[1] Retained in committee files.

also tend to imply that variations in pacemaker prices are due to marketing efforts and costs, rather than to the sophistication of the pacing device. This is untrue.

1. The Sophistication of Modern-Day Pacemakers

The paper's implication that all pacemakers are similar evidences little regard for the fact that over the last 4 years, multiprogramable pacemakers have been used widely and successfully. The more advanced dual-chambered (physiological) pacemakers have created a broader variety of options than ever before available for cardiac care. No longer are pacemakers as generic as they were years ago. Gordon, P. et al., "Multiprogramable Pacemaker Technology," The Third Decade of Cardiac Pacing 127–143; Vera, Z. "Recent Advances in Programable Pacemakers," 66 American Journal of Medicine 473–483 (1979).

Commercially available pacemakers have various configurations and a myriad of uses. Since 1976, these devices have evolved from the Xytron-type mercury-zinc epoxy units (with which Medtronics and Cordis experienced serious systemic reliability problems and recalls in excess of 40,000 units in 1976–77) to hermetically-sealed lithium iodide batteried pacemakers. These new batteries have revolutionized pacemakers, increased their lifespans by many years, and greatly improved their reliability. Pacemakers now are differentiated by their electrophysiologic modality, the design and physical implementation of their electronics, and the programing and monitoring capabilities of their ancillary equipment.

The latest Intermedics success is its development of the first permanent cardiac pacemaker that can be programed and controlled by a computer. This pacemaker will use a custom low-power microprocessor that has taken Intermedics 3 years to refine. With this type of pacemaker, attending physicians are able to select a large number of physiologic modes after implant, and even reprogram the pacers in vivo to the specific prescription of the individual patient. Physicians also will be able to change any one of 3,375 separate parameters in a noninvasive manner. Thus far, the acceptance of programable pacemakers by the medical community has so changed the marketplace, that 95 percent of all pacemakers implanted are now programable in some aspect. Just 7 years ago, in 1975, fewer than 10 percent of all pacemakers were programable. References on the technology of programable pacemakers are found in the studies numbered 4, 12, 26, 35, 37–38, 41, 44, 47, 55, 80, 88, 91 and 94 in the attached bibliography.[1]

These advances permit pacemakers to be readily adapted to the patient's ever-changing condition without additional and costly surgery that, in most instances, would be billed to medicare. Many achievements have been made in an effort to respond to physicians' suggestions for improving patient care. See, e.g., Fisher, J. D. et al., "Role of Implantable Pacemakers in Control of Recurrent Ventricular Tachycardia," 49 American Journal of Cardiology (1982); Furman, S., supra; Harthorne, W. T., "Historic Milestones of Electrotherapy and Cardiac Pacing," 23 Progress in Cardiovascular Diseases 389–392 (1981); Hauser, R. G., supra; Joseph, S. et al., "Long-Term Atrial Pacing for Sinus Node Disease with OutPut-Terminal Programable Pacemakers," 78 Journal Thoracic and Cardiovascular Surgeons 292–297 (1979); Wright, K. E., "Artificial Pacemakers, Indications and Management," XLVII Circulation 1108–1118 (1979). In fact, industry sources estimate that multiprogramability can eliminate about 25 percent of all additional pacer surgery. (See Griffin, J. C. "Pacemaker Programability: The Role of Non-Invasive Pacing System Revision," Stanford University Medical Center, Stanford, Calif.; Hanser, R. G., "Impact of Advanced Technologies on Clinical Pacing," 34th ACEMB Proceedings 196 (1981); Levine, P. A., "Why Programability?: Indications for and Clinical Utility of Multiparameter Programable Pacemakers," Pacesetter Systems 5–6.

Although these advancements will result in more significant savings for medicare, the staff's paper is silent on the subject.

2. Many Basic Costs Involved in Pacemaker Manufacturing

All the pacemaker advancements discussed in the previous section obviously have significant cost ramifications. The paper generalizes that direct manufacturing costs of pacemakers range from $600 to $900. There are two shortcomings to this estimate, however. First, it implies that all pacemakers are essentially indistinguishable, whether in terms of costs, capability, or effectiveness. Second, the paper implies that the direct manufacturing costs are the only cost items legitimately includable in calculating a pacemaker's sales price.

Actually, the sophisticated and highly reliable pacemakers of today cost very little more, and often less, than the rudimentary and less reliable pacemakers of 7 years ago, when analyzed on the basis of real dollars per year of pacing. For example, a

[1] Retained in committee files.

mercury-zinc-powered, nonprogramable pacemaker (such as the Medtronic Xytron) cost approximately $1,200 in 1975. In today's dollars, the same unit would cost about $2,000. A comparable nonprogramable pacemaker of modern design costs approximately $2,600, but lasts twice as long in service as a pacemaker of Xytron vintage. In comparable dollars, therefore, a patient would require two Xytron-type pacemakers over a 5-year period at a cost of $4,000, versus one modern pacemaker at a cost of $2,600. Put another way, a pacemaker which could be manufactured in 1965 for $750 can be manufactured today for only $100 more, assuming a 10-percent inflation factor per year. Furthermore, during this same period, the pacemakers' performance and reliability have improved, and their lifespan has increased from 2 to 8 years or more.

These cost figures just quoted represent only the direct cost of making one pacemaker unit as reported under standard accounting procedures (direct materials, labor and manufacturing overhead costs). There are many other costs associated with a company's business needs that must be included in an income statement of a corporation. These include:

The cost of researching and developing the product.

The cost of inventorying the product until revenues are received.

The cost of complying with Federal regulatory requirements for safety and efficacy, as well as good manufacturing practices before, during, and after marketing the product.

The costs of bearing risks inherent in making and selling a medical device that is as complex and sophisticated as a pacemaker and its associated equipment.

The cost of a warranty reserve.

The corporation's general and administrative costs; and

Distribution costs.

Some of these items are discussed briefly below.

(a) *Research and development costs.*—As discussed previously, application of space-age technology in the research and development efforts of Intermedics and other pacemaker manufacturers has resulted in pacemakers with extended lifespans, smaller sizes, and greater versatility and reliability. This technology was not developed inexpensively. For example, Intermedics' estimate for development engineering and testing of the company's new fully automatic pacemaker, "Cosmos," will approach $10 million over a 3½ year period.

(b) *Inventory costs.*—A significant cost that faces intermedics constantly is the cost of inventorying its products until revenues are received from their sale. The reason these costs are higher for a pacemaker manufacturer than, for example, a furniture manufacturer, is that hospitals generally do not purchase pacemaker inventories ahead of time. Therefore, Intermedics must carry the inventory costs for the period between the time that the hospitals purchase the manufacturing components until they remit the payments to Intermedics *after* implant. This period generally runs 6 months or longer. Further, as implants typically are performed on short notice, Intermedics is obligated to maintain substantial inventories at implanting centers.

(c) *Federal compliance costs.*—Another significant cost item, hardly mentioned in the staff's paper, is the amount Intermedics incurs to comply with mandatory Federal health care regulations. The paper does describe the Federal Food and Drug Administration ("FDA") regulatory programs involved in pacemaker therapy: standards for performance, safety and labelling of medical devices; mandatory manufacturing methods for medical devices; manufacturers' licensing requirements; evaluation of manufacturers' claims of new products; premarket clearance of new medical devices; and requirements for clinical investigation of new pacemaker devices (see pages 13–18). There has been no attempt in the paper, however, to cost out the burden on pacemaker manufacturers to comply with all these Federal requirements. Evidently they merely are lumped in with "general and administrative" costs from which one can infer anything, but can learn nothing.

In fact, the cost impact of Federal compliance efforts is high and pervasive, particularly during periods when new pacemaker prototypes are developed. A most unfortunate and expensive impact of the Federal compliance requirements is the long periods of time that elapse between development of a new product and obtaining FDA approval for marketing. This lag is increasing as regulations become more and more stringent. As a result, the cost to maintain Intermedics's development activity falls more and more on products now being sold, thereby raising their cost to consumers.

The costs of compliance affect virtually every company activity, and therefore are difficult to quantify separately. To the extent that it can, Intermedics has tried to estimate its compliance costs and has found them to represent normally about 5

percent of the company's total annual revenues. This year, however, these costs will approach 8 percent.

Another cost factor not discussed in realistic terms in the staff's paper is the mandatory FDA clinical evaluation requirement for medical devices, such as pacemakers (see pages 18, 19). This is an excellent program because it permits actual use testing of pacemaker devices rather than simply laboratory or simulation testing of the product. The paper's allegation that the program is manipulated by pacemaker manufacturers to short-circuit FDA premarket approval procedures is inaccurate and seriously discredits this important Federal regulatory effort.

The FDA requirement for clinical evaluation of new pacemaker devices by acknowledged medical experts has formalized the type of medical evaluations that were undertaken by the private sector over 30 years ago. Clinical investigators historically have been paid either on a yearly grant basis or on a project basis to evaluate the safety and efficacy of drugs and medical devices destined for the general public.

Intermedics has 34 paid physician consultants and one registered nurse consultant to help evaluate new products developed in the company's pacing and nonpacing operations. These consultants represent a minute fraction of the 17,000 cardiovascular surgeons, cardiologists, osteopathic cardiovascular surgeons, and osteopathic cardiologists in the United States. These are dedicated individuals whose professional reputations have now been sullied by the paper's generalized allegations.

The allegation that "consultant agreements were used to camouflage inducements to physicians" (see page 42) is false. All of Intermedics' clinical evaluation consultants are paid on a fixed periodic basis, not on the basis of numbers of pacemakers implanted. And, none of the pacemaker consultants have been paid for their services by the issuance of Intermedics stock.

(d) *Risks associated with high-risk electronic equipment.*—The short product lifecycle of pacemakers and their associated electronics has few if any parallels in the medical field. Indeed, the pacemaker is most comparable to other electronics-oriented products for which rapid technical advancement is mandatory to remain competitive. Together with the regulatory and reliability requirements imposed on pacemakers, these technological aspects introduce a high level of risk in this business. The possibility of recalls compounds the manufacturer's risk, since most pacemaker firms depend on their pacemaker lines for the vast majority, it not all, of their income.

Intermedics, like other U.S. corporations, endeavors to provide its investors a return in proportion to the risk of their investment. Therefore, the company seeks an after-tax income of 10 percent of its revenues. This level of profitability typifies the computer industry as well; for example, firms such as IBM, Digital Equipment Corp., and Apple have the same levels of profitability. Pacemakers resemble computers in the volatility of the technology and the risks associated with bringing new products to market, just as their respective profits suggest. The contention of the staff paper that pacemaker profits are excessive fails to recognize these basic considerations.

The paper's use of the Madeline Garman case (see page 20) illustrates the meaning of the risk/reward concept perhaps as well as anything. Amtech, the company that manufactured Mrs. Garman's first pacemaker (and which was not affiliated in any way with Intermedics, contrary to the staff's initial allegations), went bankrupt prior to a recall that included Mrs. Garman's unit. Amtech was not available to honor its warranty obligations; Intermedics did so voluntarily. The point here, however, is that the recall risk requires a higher return than less risky businesses.

To summarize, there is more to the cost of manufacturing pacemakers than apparently meets the committee staff's eyes. Intermedics' best estimate is that its costs for research and development, financing of inventoried products, Federal regulatory compliance, and covering risks amount to an additional 45 to 50 percent of the "direct" manufacturing costs for materials, labor and overhead.

3. Utilization of Pacemakers

The staff paper's underestimation of the value of pacemakers seems also to have colored its conclusions as to patients' need for pacer implants. In particular, the statement that as many as 30 to 50 percent of all implants are "unnecessary" is extraordinary and borders on irresponsible reporting. In a slanted recital of pacemaker overutilization, the staff lists a number of studies on pacemaker implantations (see pages 51–52). The apparent implication is that various physicians, hospitals and knowledgeable citizen groups have performed thorough research and concluded that almost half of all pacemaker implants may be unnecessary.

A truer analysis of this and other empirical evidence is that many more implants are necessary than are indicated by the miniscule samplings and final discharge diagnostic reports on which most of the studies by the staff were based. Analyses of larger patient samplings and on patients' complete medical records (including working and actual diagnoses) would reveal far lower percentages of pacemaker overprescription (see sources numbered 19, 20, 21, 49 and 74 in the attached bibliography).[1] In addition, better ambulatory monitoring devices now available will most likely (based on early results) result in a greater number of patient cases that indicate pacemaker therapy.

As questionable as the paper's reporting of overutilization is its discussion of inflated costs associated with allegedly unnecessary pacemaker implants. The paper asserts that the cost of implant surgery and followup monitoring ranges from $10,000 to $18,000. The facts are, however, that overall pacemaker costs have decreased over the last 15 years.

While these cost items have barely increased the sales price of pacemakers, they have tremendously reduced the overall expense of pacemaker therapy. There has been a significant decrease in subsequent pacemaker operations as a result of the use of integrated circuitry, lithium batteries, improved pacemaker lead technology, and great advances in shielding the circuitry from environmental interference. For example, during the period since 1965, a heart patient would have required eight pacemaker implants at $1,000 to $1,500 per device. Today, only one technologically advanced pacer would be necessary. Consequently, the cost of initial implant surgery has been cut in half. The 1965 average cost of surgery was $14,680; in 1980, it was down to $7,300. Furthermore, the total cost for surgery and followup care has declined during the same period from $20,725 to $11,259.

Another way to appreciate the decrease in subsequent operations is to look at the decrease in the pacemaker replacement market from 1975 to present. In 1975, 42.9 percent of the total sales of pacemakers were replacements. In 1982, the percent of replacements has fallen to 12.2 percent. A second indication of the reduction in the replacement rate due to technological advances is to compare the new-to-replacement implant ratio. In 1975, 1.33 new pacemakers were implanted for every replacement. In 1982, there was only one replacement pacemaker implanted per 7.20 new implants. (See studies numbered 95–98 in the attached bibliography.)[1]

Intermedics conservatively estimates that the lower replacement rate saves more than $290 million annually in health care costs when today's products and practices are compared to those of 1975. In other words, pacemaker care today is much more cost-effective than it was in 1975, higher prices notwithstanding. Moreover, Intermedics estimates that multiprogramable pacemakers have decreased reoperations by 25 percent per year. This decrease in surgery costs, and increased reliability of pacemaker circuitry, batteries, and manufacturing methods have resulted in substantial savings to the Federal Government and the medicare program. (See sources numbered 25, 37, 41, 54 and 66–68 in the attached bibliography.)[1] Nevertheless, hardly a word was written about these cost savings in the information paper.

4. Ancillary Monitoring Equipment

Pacemaker therapy involves more than just the pacemaker device itself. Integral to effective operation of the pacer is the ancillary equipment that programs the new multiprogramable pacemakers and the telemetry equipment that permits monitoring of implanted pacing devices. After years of development, integrated circuit technology and new design philosophies now enable sophisticated pacemakers to perform the following functions: EKG sensing and noise detection, output pulse generation, programing in vivo, receiving telemetry in vivo, redundant backup systems to detect transmission errors and ensure patient safety, and organization of control circuitry.

Telemetry is an integral part of Intermedics' more sophisticated pacemaker systems. It is the link for transmitting information from the pacemaker to an external receiver. Though still in its infancy, telemetry already issued in a variety of systems, with such diverse transmission means as radio frequency, inductive or magnetic coupling, and reflected inductance. Del Marco. C.J., "Lithium Pacers with Self-Contained Multiparameter Telemetry: First Year Followup," Proceedings of the VIth World Symposium on Cardiac Pacing Ch. 28–1 (1979). At least three types of data now telemetered from pacemakers include: Digital data telling the user how the programable parameters are adjusted; analogue voltage measurements decodable to inform the user of the various electronic parameters of the pacemaker's per-

[1] Retained in committee files.

formance (such as remaining battery capacity, current drain, pulse voltage, charge and current being delivered to the heart); and special signals transmitting the actual encardial EKG signal that appears across the pacemaker leads. Furman, S., "Pacemaker Longevity," 31 The American Journal of Cardiology 111-113 (January 1973).

In the near future, additional telemetry data will be available: event markers that tell the clinician when different decisions have been made by the pacemaker in response to sequences of detected EKG complexes; and accumulated data on past operating history similar to Holter monitor data. Lister, J.W., The Fourth Decade of Pacing: Technology For Better or For Worse 479-487.

Provision of ancillary equipment such as transmitters, programers, adapters, electrode splice kits and pacing cables, is a necessary cost of doing business. Historically, all pacemaker manufacturers have made available this essential equipment to hospitals, physicians, and patients. Since this equipment is not billed directly, its costs must be recovered through revenues generated by pacemakers and leads. Particularly the programers, analyzers, and receivers are expensive to design and manufacture. For example, the cost of materials, labor and factory overhead associated with a pacing programer is about $1,500. If physicians select programable pacemakers for implant, the programer is an essential component of the therapy. Yet many physicians and hospitals do not want to purchase this equipment. Often, they are reluctant to use improved technology when they have not recovered their investment in old technology. Therefore, Intermedics makes the equipment available to physicians so as to help, not hinder, the improvement of the pacing device itself and the patient's health as pacemaker technology rapidly changes. The company capitalizes the equipment and depreciates it on its financial statements in accordance with accepted accounting practices.

Completely incorrect is the staff paper's allegation that this ancillary equipment, particulary programers and transmitters, is supplied free of charge as an inducement to physicians and hospitals to order Intermedics products. Physicians and hospitals already know the equipment is essential to the proper operation of an implanted pacemaker, and they receive no benefit or value from the equipment. The benefit is derived solely by the patient who will have access to a more sophisticated medical product.

In the case of the transmitters, Intermedics provides these devices directly to patients without direct charge to them to help monitor their pacemakers themselves. This is not an improper inducement or kickback to the physician; indeed, the transmitter is not provided to the physician but to the patient. There are currently over 14,000 patients being monitored on Intermedics' free Trace-A-Pace service, a service that could be reimbursable by medicare but for which Intermedics does not charge. The savings to medicare on this service alone is estimated to be approximately $3 million a year.

III. Education and Training in Pacemaker Capabilities

Intermedics places a great deal of importance on education and training—of its scientific and engineering staff, its salaried sales personnel, its independent sales representatives, and the physicians, nurses, hospital and laboratory technicians who are involved in pacemaker therapy to any extent. This section describes briefly the quality, breadth and purpose of Intermedics' training efforts. The company finds it essential to emphasize this subject, because it was either derogated or inaccurately discussed in the staff's paper.

A. Training of Sales Representatives

One of the most serious misimpressions fostered by the paper is that pacemaker sales representatives are no different—and perhaps worse—than ordinary salesmen of used cars or encyclopedias. One of the many blanket accusations about pacemaker salespeople is found at page 62 of the paper which states in a flippant manner: "Bidding for sales representatives rivals baseball's free agent free-for-all. Salaries range from around $50,000 a year to several million dollars a year." The implication that all pacemaker salespeople are merely hucksters is false, insulting, and damaging to Intermedics' sales force, as well as to physicians and their patients who want or need to rely on these pacemaker experts.

The fact is that Intermedics' sales representatives generally are well educated (usually in the sciences, engineering, or marketing), and very experienced in medical device technology and sales. Intermedics, like other pacemaker companies, searches for the best and most experienced salespeople it can find. If new sales personnel need additional training, Intermedics ensures that they receive it. For exam-

ple, the company's estimated fiscal year 1983 budget for sales training is over $1 million.

When sales representatives are highly skilled, Intermedics is willing to and must pay good salaries or offer generous commissions, but hardly on the order suggested in the information paper. While a typical Intermedics' sales representative's yearly gross income may seem quite comfortable, he must pay for his own benefit package of health coverage and other plans, as well as his travel and operating expenses. That brings the average net salary in the $40,000 range. And, as a final note, the nature of the pacemaker business requires that a representative be available 24 hours a day, 7 days a week, thus greatly reducing his pay when computed on an hourly basis.

B. TRAINING OF PACEMAKER PHYSICIANS

No less attention is paid to the proper training of physicians who will implant pacemakers or other medical personnel who will handle, program, and monitor pacing devices and ancillary equipment. Such Intermedics training efforts usually include seminars and field training sessions. Most often training is in the field. Sales representatives will visit physicians' offices, or advise or assist them and other medical personnel at their hospitals. On occasion, Intermedics will host training seminars at its manufacturing and research facility in Freeport, Tex.

The total number of physicians who visited Intermedics' factory on representative-sponsored visits over the nearly 3-year period from January 1980 to October 1, 1982 was 377 doctors. This represents less than 1 percent per year of the 17,000 physicians in the specialty Intermedics serves.

While incredible to some, it is generally true that training of physicians in the usage, application, and technology of pacemaker implantation is not a part of the curricula of medical schools, or internship, residency, and fellowship programs, either in surgery or cardiology. Unless physicians have an individual interest in pacemaker therapy, or happen to work in pacemaker centers, they often find themselves without any usable background in pacemaker-related therapies. The lack of training usually is manifested the first time a physician is confronted with a pacemaker patient in the office or, worse, on a hospital bed or surgery table. If such is the case, an experienced pacemaker representative is a most welcome advisor.

After successfully establishing, in 1969, the first industry training program for Medtronic sales representatives, the designer of these training programs came to work for Intermedics, and is still in its employ. Soon after these field representative training programs were established, physicians began asking representatives of the pacemaker firms to help them train their nursing and resident staffs. Most pacemaker companies now promote training efforts to improve the quality of medical care for the users of pacemakers.

So widespread are the needs and requests for training that an integral part of Intermedics' technical activities within its clinical engineering division is its emphasis on the various elements of training. Training is pursued on both a formal and informal basis.

Informal training is part of every technical interaction with a physician, whether or not he or she is an acknowledged expert. Intermedics spends as much time training the physicians as it does their assistants. Training is not, and cannot be, safely restricted to inexperienced physicians interested in initiating a pacemaker practice.

Formal training programs utilize a number of different approaches. Most formal training programs organized and coordinated by Intermedics generally include physicians who are acknowledged experts. Commercial implications and references are consciously avoided. The vast majority of formal training programs, provided by a host of sources ranging from hospital or medical center sponsorship to American Heart Association or American College of Cardiology sponsorship, utilize training aids developed and provided by Intermedics. These training aids range from tutorial materials, such as slides or movies, to pacemakers, programers, transmitters, receivers, and recorders.

Specific "hands-on" training programs have been developed by both manufacturers and physicians. The programs developed by physicians generally are conducted with financial support from the manufacturers. Intermedics' animal laboratory is widely utilized for hands-on training for physicians, as is Medtronic's. Contrary to the staff paper's allegations (see, e.g., page 63), these training programs are not designed to induce a physician to use an Intermedics pacemaker. Rather, they are to help physicians and other medical personnel learn techniques and methods for providing better medical care to pacemaker patients.

IV. Alleged Abuses and Medicare Reimbursement

With a greater appreciation for the complexities of pacemaker technology and the need for experienced personnel to educate users of pacemaker equipment, the staff paper's allegations of fraud, waste, and abuse may be viewed in a more proper perspective. As noted previously, the paper is not a true survey of industry practices. Instead, it is a compilation of anecdotes about incidents, statements that are hearsay, and inferences of wrongdoing based on this collage of materials. Misimpressions easily are formed when based on half-truths about myriad parties and transactions. An unfortunate example of this problem is the paper's quote of a source named J. Richard Stanley, identified as a "former Intermedics salesman." While it is true that Mr. Stanley was employed by Intermedics in 1975, and he terminated in 1977, he was not a salesman, but rather was the supervisor of the company's sales order and shipping departments, and he never sold a pacemaker as an Intermedics salesman. Therefore, his statements to the committee staff about allegedly improper selling practices could not have been based on his personal knowledge and experience, but only on rumor and hearsay.

In the following sections, Intermedics will correct the staff paper's misstatements about the company, so that the committee will have as accurate a record as possible for its deliberations.

A. Availability of Essential Ancillary Pacemaker Equipment

The allegations that Intermedics improperly has loaned ancillary equipment to physicians and hospitals are both distorted and inaccurate. This equipment is provided *not* as an inducement to purchase Intermedics products, but as assurance that pacemaker patients will have proper access to programing and monitoring equipment essential to their recovery and sustained good health. A full discussion of this topic is presented in section II–B–(4) above.

B. Requirements for Business Travel and Training Seminars

Also discussed at length above in section III are the purposes and need for seminars and training sessions on pacemaker therapy, implantation, and monitoring. Addressed here is use of Intermedics' facilities and transport to enable the company to host these training sessions and other business-related meetings for physicians and others in the medical field at the Freeport, Tex., plant.

The staff paper refers to Intermedics as the "most frequent offender" of "flying doctors and sales representatives around the country * * *" (see page 45). The Internal Revenue Code permits a corporation to deduct as reasonable, ordinary and necessary business expenses the costs for transportation and entertainment for business purposes. Intermedics invokes these IRS provisions, just as thousands of other businesses do when they incur legitimate entertainment and other business expenses. Indeed, a perfectly adequate explanation for the way Intermedics conducts its operations can be found in a detailed look at how the aircraft are integrated into its operations. This will provide a realistic contrast to the sensationalism associated with photographs of Intermedics aircraft in the staff paper designed to create the impression of wrongdoing.

1. Aircraft Travel Essential

Intermedics has found that, due to the remote location of its corporate headquarters in Freeport, Tex. (on the Gulf Coast about 70 miles southeast of Houston), company aircraft are essential to its efficient operation. Houston Intercontinental Airport is 100 miles north of Freeport, and at least a 2-hour automobile drive (longer during rush hour) to and from Freeport. Company personnel save more than 1½ hours in travel time if they can make this trip by helicopter.

Similarly, the company's corporate fixed-wing aircraft are referred to as "time machines" because they save travellers many hours of unnecessary time spent travelling or waiting for transportation or connections. Of the 14,000 airports in the United States, fewer than 400 are serviced by commercial airlines. For a corporation whose personnel and customers travel extensively, and always are pressed for time, corporate aircraft are essential to improved productivity and morale. Intermedics' business operations are nationwide, and are not exclusively in pacemaker manufacturing and medicare-related activities. In fact, a portion of the air travel by Intermedics personnel has nothing to do whatsoever with pacemakers. For example, some of Intermedics' allied business activities outside the medical device field include: manufacturing of printed circuitry boards, production of sonar computers

used in oil and gas exploration, design of new circuitry for the telephone system for the entire country of Sweden, and even circuitry for toy companies' video games.

In sum, the nature of Intermedics' corporate operations makes aircraft use essential. The primary users are Intermedics corporate personnel, although Intermedics pacemaker customers also share the aircraft at times. None of this usage is casual, however. For all its aircraft, Intermedics maintains detailed flight logs in accordance with accepted business practices, and has the logs reviewed by the company's independent accounting firm to ensure compliance with Federal requirements. Furthermore, these logs show that in fiscal year 1982, only 21 percent of the aircraft's usage was by doctors, contrary to inferences in the staff's paper.

2. Occasional Boat Usage

Freeport's primary natural resource is the Gulf of Mexico, whereas Intermedics' major competitors are located in major cities that offer extensive social, cultural, and recreational facilities. Therefore, Intermedics occasionally utilizes a fishing boat to entertain customers during visits to its manufacturing facilities. Based on 1981 log entries, the boat was used by 54 doctors out of 377 who visited. It allows sales personnel to spend time with visiting customers away from the usual disruption of office or factory activities. As with the company's corporate aircraft, however, extensive logs for each boat trip are maintained and audited for compliance with a variety of Federal tax and other reporting and maintenance requirements.

3. Limited Use of Hunting Facilities

The information paper refers (see page 71) to the company's "hunting preserve." This is another natural resource similar to the Gulf of Mexico that is available to Intermedics because of its remote location. A nearby area called the Mississippi "flyway" is well known for waterfowl hunting during the fall migration period. Intermedics leases an old farmhouse and uses it as a hunting lodge in Garwood, Tex., which is approximately 96 miles from Freeport, Tex. Prior to its use by Intermedics, the farmhouse could have been rented as a residence for about $100 a month. It now is used from November 6 to January 25 each year, and was visited by 127 doctors during the 1981–82 hunting season.

As with the company's corporate aircraft and boat, extensive logs for each visit are maintained and audited for compliance with Federal reporting requirements.

C. RESPONSE TO KICKBACK ALLEGATIONS

The most serious allegations included in the staff paper are that kickbacks have been made to physicians in return for use of specific pacemaker products (see pages 41–47). Below are Intermedics' responses to these allegations in the order that they appear in the paper on pages 41 and 42.

1. No Cash Kickbacks Given

Intermedics has not offered any cash kickbacks to physicians for use of its products.

2. No Stock or Stock Options Offered Doctors as Inducements to do Business

None of Intermedics' pacemaker medical advisors, nor its pacemaker physician customers, have been offered or given stock in Intermedics. Furthermore, only the board of directors may authorize an offer of any kind of stock option; totally false are any allegations that the vice president of marketing or vice president of sales could take such an action.

3. Consultants' Compensation of Clinical Evaluation Rendered, Not to Camouflage Payments to Doctors

The paper's allegation that payments of $200 to $20,000 are paid for clinical evaluation is totally false. Intermedics retains physicians to evaluate new products and compensates them periodically for their services. These consultants are paid strictly for their services, not to induce them to purchase Intermedics' products or to pay them kickbacks. The services rendered are a common, well established practice in the health care industry, in accordance with clinical testing procedures required by Federal law. (See section II–B–2(c) for a complete discussion of the FDA clinical evaluation program.)

4. No Rebates Intended for Patients Are Sent to Physicians

Intermedics does not send rebates to physicians to which patients are entitled. In fact, the company has an established corporate policy to send the patient involved a copy of every payment made to either a hospital or physician. This policy assures that all patients are aware of all payments made in their behalf so that an improper payment cannot result from the reimbursement.

The following allegations of indirect kickbacks are set forth on page 44 of the paper.

5. No Company Credit Cards Given

No physician customers have been issued Intermedics corporate credit cards.

6. No Payments to a Pennsylvania Physician for Every Initial Implant

The $150 payments alleged were not made by Intermedics.

7. No Stock Offered at Reduced Prices

Intermedics has not offered stock or stock options to any pacemaker physician at any reduced price.

8. No Payments for Unreimbursed Medical Expenses Without Required Documentation

Intermedics does not pay $300 to $500 or any amount, for unreimbursed medical expenses without detailed warranty reimbursement documentation procedures, as discussed in section VI below.

9. Previous Entertainment Fringe Benefits

At one time, Intermedics, like other pacemaker manufacturers, sponsored a Texas BBQ and arranged for Doc Severinson's band to play at the American College of Cardiology meeting in Houston in 1980. The purpose of these functions was to entertain physicians attending the meeting. Such business entertainment activities are no different from cocktail parties sponsored by corporate members of trade associations when the association gathers for its annual meeting. Nevertheless, at the request of the American College of Cardiology to cease these activities in 1981, Intermedics complied. The company has not sponsored such events since that time, although other pacemaker manufacturers may have done so.

10. No Travel Inducements

The allegations of luxurious trips sponsored by each of the pacemaker manufacturers is a blatant example of the staff paper's sweeping indictments of all, when only one or two of the companies actually may have engaged in the allegedly improper activities. To set the record straight, Intermedics has not participated in any of the travel events listed on page 46 of the information paper. Specifically, Intermedics has not participated in ski trips to Vail and Europe, vacations in the Caribbean, trips to Australia, gambling junkets to Las Vegas, or salmon fishing in Alaska.

11. No Gifts as Alleged

The paper makes several sweeping allegations on page 46 about "gifts" pacemaker manufacturers are said to bestow. Intermedics did not give gold-plated shotguns to cardiologists in Georgia, nor has the company ever leased luxury cars to "cooperating" physicians, as described in the paper. Intermedics also has not repeatedly given tickets and accommodations to physicians to attend the Indianapolis 500 race. Rather, the company has sponsored physician training seminars, conducted by pacemaker physician experts and some of the engineering staff of Intermedics, the day before the Indy 500 in 1981 and 1982. The primary purpose for the Intermedics association with high technology automobile development and advertising is to promote the name "Intermedics" and expand its non-pacemaker product lines, including electronics, high-temperature carbon coating, oil field computers and other products, and water purification technology. Guests of Intermedics who have attended races have included executives from its high technology customers and physicians who have a personal interest in automobiles. The agenda for these product training seminars has focused on the most advanced technology in the pacemaker industry (see

program agenda attached as exhibit A[1]). Whereas some pacemaker manufacturers' seminar agendas schedule only 2 hours of meetings during 2 days of recreational activities (see, e.g., Medtronic program agenda attached as exhibit B[1]). Intermedics' agenda devotes many hours of "hands-on" training sessions for physicians to learn to operate Intermedics' new pacemaker programers and equipment. In addition, lectures are given by company engineers on the status of various Intermedics products in clinical trials. The training and information provided generally is not available in a medical school or training format to which doctors would otherwise be exposed, as explained in greater detail in section III above.

V. Products Reliability

The most damaging as well as unsubstantiated allegations in the paper are those that call into question the reliability of pacemaker devices. It is these groundless reports that have caused patients to cancel their implants for fear of their failure. One such irresponsible statement, found on page 27 of the paper, states that an Intermedics device "could result in atrial fibrillation." Although theoretically this problem could arise, it is a well-known risk of asynchronous pacing in the atrium. It is not a defect in the design or manufacture of the pacing device itself. In fact, there have been over 10,000 implants of this particular device with little or no documentation indicating that atrial fibrillation has occurred.

A second reckless over-generalization is the paper's discussion of potential problems with polyurethane insulated leads attached to pacing devices (see page 27). The staff's assumptions are based on information taken out of context, and are not supportable by empirical evidence. The facts are that polyurethane material has been extensively investigated and tested in the artificial heart program. Intermedics has implanted approximately 34,000 polyurethane leads over the last 3 years without a single insulation failure to date. Medtronic and Cordis also use polyurethane leads. Cordis reportedly has seen no problems, and Medtronic has seen only a very low incidence of problems. Even with these problems, Medtronic's failure rates are much lower than those with silicone rubber leads. Indeed, it is the properties of polyurethane (high strength and a low coefficient of friction) that have made possible the day-to-day use of dual chamber (physiological) pacers.

Third, and quite outrageous, is the staff's proposal that used pacemakers be refurbished and reimplanted. The staff suggests significant cost savings would be realized and it expressed disappointment that the quick response in the field to reuse has been that the FDA will not allow it (see page 37). Never did the staff bother to research FDA guidelines on the issue; rather, it relied on the opinion of one FDA spokesman to try to dignify the concept of refurbishing pacemakers. In fact, FDA compliance guideline No. 7124.12 objects to the practice of reuse of cardiac pacers, for the following reasons:

"* * * there is a serious question whether pacemakers can be properly resterilized following initial implantation due to the possibility of body fluids entering the terminal leads of the pacer. This also poses the problem of foreign protein matter to the second recipient."

A fourth and totally false charge in the paper is that "most defective devices are discarded and never returned to the manufacturer" for analysis (see page 28). To the contrary, Intermedics recently checked its explant records and found that of 616 explanted pacers, all of which were confirmed to have been replaced with Intermedics pacemakers, as many as 354 were returned for analysis. This gives a return rate of 57 percent, proving the allegation to be inaccurate. Furthermore, Intermedics analyzes all returned pacemakers to determine mode, mechanism, and cause of failure. This review program has been in place since shortly after the company began distributing pacers. Seventy-four percent of all returned pacemakers are found to function within their original specifications. The company uses the results of these analyses not only to determine grounds for credit reimbursement, but also to enable its engineers to develop contingency plans for corrective action if any systemic (nonrandom) failure occurs.

To summarize Intermedics' record on product reliability, two points must be emphasized. First, normally the company finds that 74 percent of all its returned pacemakers function within their original specifications. Second, the failure rate of its pacemakers is far below (one-tenth) the failure rate of .15 percent per month accepted by the Atomic Energy Commission for implantable pacemakers; this translates into 98 percent survival probability over 11 years' operation. Third, Intermedics does not reuse pacemakers because it is not safe. And fourth, Intermedics' pacemak-

[1] Retained in committee files.

ers have an excellent record in reliable performance, a fact which never came to light in the information paper.

VI. Warranty Policy

The staff's information paper contains numerous allegations regarding the warranties issued on pacemakers. Intermedics would like to address these allegations to demonstrate the extent of their inaccuracy in the case of Intermedics' pacing devices. The second half of this section will explain Intermedics' warranty procedures.

A. WARRANTY EXPERIENCE

The staff paper variously described pacemaker manufacturers' warranties as "deceptive, dishonored, and inappropriately limited to subordinate the manufacturer's liability to medicare," "a sham, a marketing gimmick, at best, and at least in some cases camouflage for kickbacks and rebates," or "an opportunity—the incentive to 'trade up' " (see pages 56–57). The paper also recounts, in a rather distorted fashion, Intermedics' purchase of the failing Arco pacemaker line in 1980, as well as its purchase offer to American Pacemaker in 1982. The paper criticized Intermedics for sending a registered letter in August 1981 to physicians who had implanted three Arco models. The letter, however, informed the physicians that the pacemakers had been exhibiting premature battery depletion. It also recommended replacement of the pacers at the discretion of the physician, by the 34th month after implant, if explant was not contraindicated by the patients' medical condition. In the same letter, Intermedics promised to honor Arco's reimbursement policies and provide "expanded options" for replacing Arco's models. The staff paper alleges that the letter merely presented Arco physicians the uncomfortable choice of leaving potentially defective units in the patients, or replacing the units with Intermedics pacemakers and being locked into dealing with that firm.

Intermedics' pacemaker warranties are substantially similar to other manufacturers in that explanted pacemakers must be returned to Intermedics so that the explanted device may be analyzed to ascertain if the unit has failed. Intermedics entered the industry in 1975 at a time when warranty policies and practices were well established. In order to meet competition pressures, Intermedics adopted warranty policies that enabled it to compete with the established companies. (See warranty agreements, attached as exhibit C.[1])

In 1980, Intermedics and other companies entered into negotiations with Arco to purchase certain assets and assume warranty obligations with the knowledge that deficiencies existed in certain of Arco's products. Arco management recognized its long-term warranty responsibility to patients and physicians and insisted that the acquiring company agree to honor its warranties. They also had certain requirements regarding the financial strength of the company to assure long-term fulfillment of their warranty obligations. A component of the negotiated purchase agreement was that the acquiring company would establish a warranty reserve. Intermedics created such a reserve, ensuring that it would honor Arco patients' pacemaker warranties. (See Intermedics' 10K report, schedule VIII, attached as exhibit D.[1])

Intermedics fully evaluated the Arco products and physicians' reports. On the basis of this assessment, Intermedics decided it should send out a product advisory letter on three Arco models to ensure patient safety from the risk of sudden pacemaker cessation. The letter outlined the potential problems and recommended that the pacemakers be replaced, electively, at 34 months. Intermedics made this recommendation for two reasons. First, it sought to avoid the substantial risks associated with sudden cessation of pacemaker output that might threaten pacemaker-dependent patients. Second, it wanted to spare physicians the burden of having to follow a rigorous weekly monitoring program that would be costly both to the patients and third party carriers.

Intermedics' management feels that it properly exercised its social responsibility in two important ways. First, it alerted the medical community of performance modifications in the interests of patient safety, and second, it fulfilled Arco's warranty obligations. The replacement policy provided to Arco patients offered, at no charge, an equivalent pacer if the failure analysis discovered that the returned unit had depleted batteries and was still covered by its warranty. If the batteries were not depleted and the pacer was still warranted, Intermedics reduced the purchase

[1] Retained in committee files.

price of a new replacement pacer. In all cases, Intermedics offered additional coverage for the patient of up to $500 for nonreimbursed medical expenses.

Subsequent to its first advisory letter, Intermedics accumulated and analyzed additional reliability data on all Arco models. After reviewing its field reports from both the United States and Europe, Intermedics concluded that premature battery depletion without adequate end-of-service indications was an inherent problem in all Arco pacemakers with lithium thionyl chloride batteries. In addition, researchers discovered a catastrophic sudden failure mechanism in several Arco units due to the failure of a certain type of feedthrough capacitor. Therefore, Intermedics instituted a second recall of all Arco models containing these batteries. Intermedics determined that the pulse generator replacement times were essential, since the predicted condition of sudden failure was extremely hazardous to patients who were pacemaker-dependent. Intermedics developed no-charge warranty offers with a reasonable nonreimbursed medical coverage provision. The company designed these offers to fulfill its warranty obligations and to minimize the financial impact on patients.

Intermedics' management feels that it appropriately handled obligations for patient safety, and its warranty obligations.

B. OUTLINE OF WARRANTY PROCEDURES FOR INTERMEDICS

When Intermedics receives a removed pulse generator, it forwards the device to its product assurance department for evaluation. After analysis is complete, the department prepares and sends its copy to the Intermedics' sales department and one to the party who returned the pulse generator (i.e., the hospital, patient, or doctor).

The party invoking the warranty rights may request monetary reimbursement upon receipt of the failure analysis report, if the report indicates premature failure of the device while it was still under warranty. When Intermedics receives a request for warranty payment, if drafts a credit order and/or a credit memo. The company does not issue a payment, however, without either the credit memo or the credit order. All payments Intermedics makes on a warranty claim are by an account credit to the party who requests the warranty reimbursement. The credit memo, for example, will credit the hospital account and also list the patient name on the credit memo whenever possible, so that two endorsements will be on the reimbursement payment.

The only time a doctor's name might appear on a warranty credit memo would be if the physician had been billed for the pacemaker in the first instance. This is a rare occurrence, however. In fact, Intermedics has only invoiced seven physicians and one clinic, directly, during the past 11 months. The total dollars billed to these physicians, directly, during this 11-month period was $110,155. Interestingly, credits paid directly to physicians over this same period were $31,695. Of this amount, $29,950 was credited to the clinic mentioned above, while the balance was credited to two of the seven physicians. It should be noted that Intermedics has 1,400 active accounts, 1,392 of which are hospitals.

This information clearly refutes the paper's accusation (see page 2) that "liberal payments of 'unreimbursed medical expenses' " often amount to "incentives to physicians to 'write [their] own rebate.' "

VII. Conclusion and Recommendations

It is the hope of Intermedics' management that the Senate committee accepts the foregoing responses to the allegations in the committee staff's information paper in the spirit in which they are offered. For Intermedics—or for any other pacemaker manufacturer maligned in the paper—to ignore these allegations by not responding, would be a great disservice to many people who have contributed to the tremendous progress made in pacemaker therapy. It also would be a derogation of what Intermedics feels is its duty to represent the best interests of the company's employees, shareholders, customers, and others who have entrusted their careers, investments, product loyalty, and faith in Intermedics.

Uppermost in our thinking, however, is that Intermedics' response will in some measure sensitize the committee to the complexities and exigencies of pacemaker therapy, policies, procedures, and business practices. Perhaps, too, after reading Intermedics' response, the committee will better appreciate the many contributions our industry has made to the general health and well-being of cardiac patients throughout the world.

No response would be complete if it did not, in some fashion, suggest alternative approaches to or remedies for the fundamental problems at hand. In our opinion, the most sensible solution would be to form a partnership among Government, industry, and medical representatives. With the knowledge and insight each would

bring to the issues at hand, meaningful decisions would be arrived at and implemented for the common good.

For our part, Intermedics is ready to cooperate in such an undertaking immediately. As evidence of that willingness, we offer for the Senate committee's consideration a sample of the kinds of changes we believe would be constructive in improving the existing medicare system. Consider for example:

(a) Medicare could establish the necessary policies and paperwork procedures to assure that pacemaker warranty payments are passed through easily and credited directly to medicare. No policies or procedures exist for this now.

(b) The committee should expand its study of medicare reform to include input from representatives of pacemaker companies, pacemaker physicians, and hospitals to ensure that its future studies and recommendations properly consider industry needs and practices.

(c) Certified audits of companies' patient reimbursement and warranty claim departments should be made once a year to assure medicare that proper procedures are followed.

(d) A medicare representative should visit each manufacturer at least once a year to inspect the manufacturing facility, ensure that proper quality assurance is in place, and product warranties are being honored.

These are representative of the kinds of changes that would signal the beginning of a new controlled, more responsive medicare system. It seems to us that the Federal Government is complaining about systems, methods, and procedures that do not exist, but for which it has the responsibility to develop. If these systems, methods, and procedures are suddenly established by those who do not understand how we have reached world leadership in medical care, a very dedicated and competent industry will be compromised.

In its assessment of possible alternatives to the present reimbursement system, however, the committee should be mindful of the fact that rigid legislative actions could discourage pacemaker and other medical device manufacturers from advancing the state-of-the-art of their products' technology. While incentives need not be excessive, they should be sufficient to encourage manufacturers to pursue their extensive investments in research and improvement of pacemaker reliability and longevity. The United States has few industries that can claim to be world leaders in their specialties. Our pacemaker industry certainly holds such a world leadership position in terms of its sophistication and utility. Thus far, foreign manufacturers have never threatened American superiority in this field. Yet, overly restrictive legislation could permit foreign suppliers easy access to the U.S. marketplace.

Technology advances that improve the quality of life for millions of individuals should never by discouraged. The committee should recognize that to design an inexpensive pacer to "low-cost bidder" specifications not only will take time and more R. & D. money, but it also will result in a mediocre and quite different product than exists today in the versatile multiprogramable pacemaker. If the committee decides that the cost of the product may be more important than its quality, performance, and characteristics, then it should so notify the American people, whose lives depend on pacemaker medical care, and allow them to participate in that choice.

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